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**Hepatitis C Screening and Treatment of Prisoners:
Analysis of Policy and Practice in Kentucky**

CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the
requirements for the degree of
Master of Public Health
in the
University of Kentucky College of Public Health
By
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With heartfelt gratitude,

Charity Faith Kranz, DO

Abstract

INTRODUCTION

The United States and the Commonwealth of Kentucky are currently overwhelmed by a triad of complex epidemics—incarceration, opioid overdose deaths secondary to substance use disorders, and hepatitis C. Research has suggested hepatitis C screening and treatment of prisoners may be a cost-effective strategy to address the hepatitis C epidemic. Since Kentucky has been particularly impacted by these interrelated health threats, further exploration of hepatitis C in Kentucky prison populations and their potential role in addressing these epidemics is warranted.

Primary Objective

The main goal of this research was to examine hepatitis C screening and treatment policy and practice within the Kentucky correctional system, specifically among prisoners, as a potential target for multidisciplinary interventions to combat the substance use disorder and hepatitis C epidemics and prevent HCV transmission.

METHODS

Scholarly and grey literature sources as well as publicly available data sources and resources about hepatitis C screening and treatment in Kentucky correctional populations were reviewed for initial analysis of pertinent policy and practice applicable to Kentucky prisoners.

RESULTS

Hepatitis C prevalence among Kentucky prisoners estimated overall mean (95% CI) was 25.8% (14.5%-37.1%), nearly 16 times that of Kentucky non-institutionalized adults, and estimates of the number of infected persons include: 5,598 (3,146-8,051 95% CI) infected Kentucky state and federal prisoners; 4,993 (2,806-7,181 95% CI) infected Kentucky prison admissions; and 4,776 (2,679-6,854 95% CI) infected Kentucky prison releases. There may be an estimated 3,967-4,568 undiagnosed hepatitis C infected prisoners in Kentucky. From 2010-2013, about one third (n=1,205, 32.4%) of the 3,724 Kentucky state prisoners screened for hepatitis C were confirmed positive, but only 175 (14.5%) started treatment, leaving 1,030 (85.5%) untreated. Kentucky prisoner screening and treatment cost estimates were from \$2.20 million (\$1.41-\$2.99 million 95% CI) and \$200 million (\$112-\$287 million 95% CI) at 50% discount for releasees, respectively, to up to \$4.89 million (\$3.12-\$6.65 million 95% CI) for one-time screening of both current prisoners and 2017 admissions with \$887 million (\$498 million – \$1.28 billion 95% CI) for treatment of infected cases. If the entire Kentucky Department of Corrections medical services budget was used solely to purchase HCV treatment regimens based on per patient hepatitis C treatment cost estimates, it could cover the following mutually exclusive options: 681 treatment regimens at the \$83,735 Kentucky Medicaid cost; 909 treatment regimens at a 25% discounted cost of \$62,801; or 1,363 treatment regimens at a 50% discounted cost of \$41,868. If the 1,030 untreated prisoners from 2010-2013 infected 1,030 community members upon release, costs to screen and treat the new cases could be up to \$89.2 million. If left untreated, the lifetime healthcare costs for hepatitis C in the 1,030 prisoners and 566-875 new community cases of chronic hepatitis C could be \$160-\$191 million.

CONCLUSIONS

For prisoners to become part of the solution of this triad of epidemics, Kentucky must strive for creative funding sources, and effective collaboration, integration of services, and multi-disciplinary interventions.

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List of Abbreviations

AASLD – American Association for the Study of Liver Diseases
 ACA – American Correctional Association
 ACCP – American College of Correctional Physicians
 Anti-HCV – hepatitis C virus antibodies
 APRI – aspartate aminotransferase to platelet ratio index
 ASAM – American Society of Addiction Medicine
 BOP – Federal Bureau of Prisons
 CCHA – Coalition of Correctional Health Authorities
 CDC – Centers for Disease Control and Prevention
 CHC – chronic hepatitis C virus infection
 CI – Confidence Interval
 CJKTOS – Criminal Justice Kentucky Treatment Outcome Study
 CPGs – Clinical Practice Guidelines
 DAAs – direct-acting antiviral agents
 DOC – Department(s) of Corrections
 DOT - directly observed therapy
 EHMs – extrahepatic manifestations
 EHR – electronic health record(s)
 FDA – Food and Drug Administration
 FQHS – federally qualified health centers
 FY – fiscal year
 H&P – history and physical examination
 HCC – hepatocellular carcinoma
 HCV – hepatitis C virus
 HIV – human immunodeficiency virus
 IDSA – Infectious Diseases Society of America
 IDU – injection drug use
 IFN – Interferon
 IOM – Institute of Medicine
 IQR - interquartile range
 KDOC – Kentucky Department of Corrections
 KDPH – Kentucky Department for Public Health
 NAT – nucleic acid test
 NCCHC – National Commission on Correctional Healthcare
 PegIFN – Pegylated Interferon
 PWID – persons who inject drugs
 RBV – ribavirin
 RNA – ribonucleic acid
 SAP – substance abuse treatment program
 SOC – standard-of-care
 SUD – substance use disorder(s)
 SVR – sustained virologic response
 SVR24 – sustained virologic response at 24 weeks
 UK – University of Kentucky
 U. S. – United States
 USPSTF – United States Preventive Services Task Force
 VA – Veterans Affairs
 WHO – World Health Organization

INTRODUCTION

The United States (U.S.) and the Commonwealth of Kentucky are currently overwhelmed by a triad of complex epidemics—incarceration, opioid overdose deaths secondary to substance use disorders (SUDs), and hepatitis C. The U.S. has the highest incarceration rate in the world, and the nation’s prison population had a 677% explosion from 1972 to 2011, rising from 198,061 to 1,538,854 sentenced state and federal inmates, respectively.^{1,2} The “silent” hepatitis C epidemic is so named for the insidious nature of both the epidemic and its causative virus, which facilitates transmission from asymptomatic infected individuals, especially among persons who inject drugs (PWID), and conceals infection for years often until chronic severe liver disease surfaces.^{3,4} Hepatitis C virus (HCV) is the most common blood borne infection and the primary indication for liver transplants in the U.S.; yet, around 75% of those with HCV are unaware of their infection.⁴⁻⁷ HCV is also deadly, contributing to more deaths in the U.S. in recent years than 60 other reportable infectious diseases combined.⁸⁻¹⁰ The U.S. SUD and opioid epidemics have resulted in more than half a million drug overdose deaths from 2000 to 2015, the majority of which (more than 6 out of 10) involve an opioid.^{11,12} Each day, the lives of 91 Americans are tragically extinguished by death from opioid overdoses.¹¹ The combination of direct, indirect, monetary, and nonmonetary costs and negative consequences of this triad of epidemics is so extensive that not a single person, family, or community in the U.S. is left truly untouched.¹³

Kentucky has been significantly affected by these interwoven epidemics, and the social determinants of health are among the frayed threads tying them together. Kentucky is leading the nation with its rate of new (acute) HCV infections, and from 2006-2015 Kentucky’s opioid overdose deaths tripled.¹⁴ Kentucky’s prison population is also among the most rapidly expanding in the U.S. with growth exceeding 260% since 1985.^{15,16}

Of particular interest, prisoners' high prevalence of both HCV and injection drug use (IDU), their high likelihood of spreading HCV in the community upon release, and their constitutional right to healthcare have distinguished them as a possible key component of an overarching solution to the interconnected opioid and hepatitis C epidemics in the U.S. and Kentucky.¹⁷

Primary Objective

The main goal of this research is to examine HCV screening and treatment policy and practice within the Kentucky correctional system, specifically among prisoners, as a potential target for multidisciplinary interventions to combat the SUD and hepatitis C epidemics and prevent HCV transmission.

Literature Review

Introduction

This literature review examines the evidence base of HCV screening and treatment policy and practice affecting U.S. and Kentucky prisoners, their relationship with the SUD and hepatitis C epidemics, and their possible role in prevention of HCV transmission. Primary literature searches were performed via databases including PubMed, Web of Science Core Collection, and ProQuest Criminal Justice, using the following search terms, key words, and phrases: prisons, jail, prisoners, Criminal Justice System, hepatitis C, HCV, screening, mass screening, prevention, preventive health services, hepatitis C treatment, United States, Kentucky, opioid epidemic, injection drug use, and persons who inject drugs. Database search results were limited to articles published in English during the last 10 years (2007-2017). Internet searches of grey literature were necessary to gather crucial resources such as evidence-based guidelines, policies,

data, statistics, and reports from government sources and professional organizations. Additional germane references were selected through secondary review of frequently cited sources, bibliographies of important references, and those recommended by authoritative sources and collaborators.

Following this introduction, historical background further describes America's "incarceration epidemic," prison healthcare, the role of litigation, identification of HCV, initial emergence and recognition of the hepatitis C epidemic in corrections, previous hepatitis C treatment regimens, incarceration and state Department of Corrections (DOC) budgets, and emergence of the current HCV and opioid epidemics. Second, an overview of hepatitis C explores HCV transmission, the natural history of hepatitis C, the goal of treatment, and treatment with direct-acting antivirals (DAAs). Third, theoretical and empirical research and information about the following topics is presented:

Epidemiology and Interrelated Epidemics in the United States and Kentucky
Corrections and the Hepatitis C and Substance Use Disorder Epidemics
Hepatitis C Screening and Treatment of Prisoners – Guidelines and Policy
Hepatitis C Screening and Treatment of Prisoners – Implementation and Practice

The literature review closes with a brief summary and conclusion about existing knowledge and related information gaps, pertaining to these topics of interest.

Historical Background

The significant increase in the U.S. prisoner population, or "incarceration epidemic," has been attributed by some to the nation's "War on Drugs" and failure to appropriately treat SUDs and mental illness as medical conditions.¹⁸ Rich and colleagues further suggested, "Deinstitutionalization of the mentally ill over the past 50 years and severe punishment for drug users starting in the 1970s have shifted the burden of care for addiction and mental illness to jails and prisons."¹⁸ Scientific research has provided sound evidence that substance use, misuse, and

addiction have a neurobiological basis and cause varying degrees of changes in the brain, indicating a SUD is actually a chronic disease.¹³ So, individuals with SUDs do not deserve to be stigmatized as immoral, lacking character and self-control.¹³ On the contrary, they are truly suffering from a chronic disease with potentially devastating consequences, rendering them in desperate need of compassion, empathy, support, and quality medical care.¹³

Litigation won prisoners the constitutional right to healthcare in 1976, requiring minimum healthcare standards codified by accreditation bodies such as the National Commission on Correctional Healthcare (NCCHC).¹⁹ This accreditation is voluntary not mandatory, and many U.S. correctional institutions have not become NCCHC accredited. Consequently, litigation has continued to serve as an enforcer of mandated minimum healthcare standards, at times, forcing improvement of the fragmented and variable healthcare prisoners receive.¹⁹

The following excerpt from the “Hepatitis C: An Epidemic for Anyone” website³ eloquently introduces HCV and its “silent epidemic”:

The identification of the hepatitis C virus in 1989 solved a growing mystery. Over the past ten years, large numbers of hepatitis victims had begun to appear, apparently with a virally caused disease. But when examined, these patients tested negative for both hepatitis A and B. The unknown disease was known as non-A, non-B hepatitis. When a test was developed in 1990 to identify individuals infected with hepatitis C, hepatitis C was found to be responsible for the majority of these cases - and it has quickly proved to present a frightening challenge.

In the late 1990s, 12-35% of prisoners were already infected with HCV by the time the hepatitis C epidemic in U.S. corrections was first identified.^{19,20} Treatments for HCV then began with Interferon (IFN) with 5-30% sustained virologic response (SVR) cure rates in the 1990s. The Ribavirin (RBV) and pegylated IFN (PegIFN) combination became available in the early 2000s, and its rates of SVR at 24 weeks (SVR24) from 40-90%, depending on HCV genotype, made it the standard-of-care (SOC) until the arrival of DAAs in 2011 and 2013.^{21,22} These earlier HCV treatment regimens were poorly tolerated, less effective, and costly, posing challenges to

correctional systems not unlike the current ones. Poor outcomes associated with the spreading epidemic and inmate litigation ultimately led to the development of the CDC's *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings* guidelines in 2003, including recommendations for HCV prevention, testing, detection, management of infection, health education, and release planning.^{19,20}

In Kentucky, the case of *Paulley v. Chandler* in 2000 was the first lawsuit in “the next wave of prisoner medical litigation.”^{23,24} Michael Paulley, an Army veteran and prisoner with HCV and cirrhosis, had an estimated 50% chance of surviving until his 2004 parole eligibility, according to his Veterans Administration (VA) physician. The Kentucky Department of Corrections (KDOC) denied Paulley's request for hepatitis C treatment, which the courts determined was due to cost, despite the VA's willingness to pay for treatment.^{23,24} As a result, in March of 2000 the KDOC was court-ordered to treat Paulley's hepatitis C; the KDOC also responded by developing an HCV treatment plan with potential to treat up to 1,000 prisoners.²³ At that time, treatment costs for IFN and RBV regimens ranged from \$8,000 to \$20,000 per prisoner per year.^{23,24} The KDOC estimated their plan would cost \$25,000 per prisoner, including labs, liver biopsies, and medications, and around \$25 million total, nearly exhausting KDOC's available medical budget.²³ The KDOC treatment plan included 8 qualifications (e.g. multiple tests for cirrhosis or other liver damage) and 17 treatment exclusions (e.g. high risk behaviors, body piercing, tattoos, sexual behaviors, parole eligibility within 18 months).²³

Regarding the “incarceration epidemic,” most state inmate populations grew over the course of 2007 with their yearend populations significantly larger than those at the year's start. The growth of Kentucky's incarcerated population, a 12% increase, surpassed all other states.¹ By 2008, it was reported that 1 in 100 adults in America were incarcerated.^{1,18} From 1987 to

2007, total state spending on corrections in the U.S., including bonds and federal sources, rose from \$12 billion to \$49 billion, and during that fiscal year (FY) period total state general fund expenditures on corrections increased by 315%.¹ In FY2007, corrections accounted for 5.2% of Kentucky's general fund expenditures.¹ Not surprisingly, inmates' medical care is among the "principal cost drivers" affecting state DOC' budgets, which is why the costs of HCV treatments, up to \$30,000 per inmate per year at that time, were a major concern then as well.¹

The *Clinical Infectious Diseases* Major Article, "Emerging Epidemic of Hepatitis C Virus Infections Among Young Nonurban Persons Who Inject Drugs in the United States, 2006–2012," revealed significant annual increases in acute HCV incidence among young persons of 13% (P=.003) in nonurban counties contrasted with 5% (P=.028) in urban counties.²⁵ Nonurban counties east of the Mississippi River were markedly affected in the 30 states (88%) out of 34 with higher incidence in 2012 versus 2006, and Kentucky was among states with a $\geq 200\%$ increase.²⁵ There were 1202 new cases of HCV, and 85% were white. Of 635 acutely infected young persons interviewed, 75% admitted to IDU, and 75% of the PWID began abusing prescription opioids roughly 2 years prior to heroin.²⁵ As previously noted, these public health threats have only continued to intensify.

Overview of Hepatitis C

HCV disease burden has been increasing throughout the world, especially in the U.S. According to the World Health Organization (WHO), HCV morbidity and mortality continue to rise worldwide with an estimated 700,000 deaths per year due to HCV complications such as cirrhosis, hepatocellular carcinoma (HCC), and liver failure.²⁶ The often asymptomatic nature of HCV infections makes it difficult to adequately assess and address the true burden of hepatitis C, perpetuating transmission from undiagnosed and untreated HCV carriers.²⁶

The primary mode of HCV transmission is via exposures to infectious blood percutaneously (through skin).^{4,21,27} In the U.S., IDU is both the main route of HCV transmission and the most important risk factor for HCV infection with 60-70% of new infections occurring in PWID.^{4,21,26,28,29} Rising rates of IDU and HCV among young persons in the U.S. and Kentucky have been associated with evidence of increased risk of perinatal HCV transmission from infected mothers to their infants.^{4,26,27,30} Historically, transfusions of blood and its products as well as organ transplants commonly transmitted HCV to recipients before such biological donations were screened in the U.S. as of 1987 and 1992.^{4,21,27} Needlestick injuries are a source occupational exposure and transmission of HCV to healthcare workers.^{4,21,27} Sexual transmission, sharing contaminated personal items, and certain invasive health care procedures are less common means of HCV transmission.^{4,21,27}

The natural history of hepatitis C infections and health effects may include acute HCV infection, chronic HCV infection, liver cirrhosis, extrahepatic manifestations, and potentially fatal complications.^{5,31} Acute hepatitis infection is often asymptomatic, but symptoms such as fatigue, abdominal pain, nausea, decreased appetite, and jaundice affect 20-30% of newly infected persons.^{4,5} Spontaneous clearance of acute HCV infection occurs in 15-25% of individuals within about 6 months of exposure.⁵ Without treatment, approximately of 55-85% of individuals with acute HCV infection develop chronic HCV (CHC) infection, which rarely self resolves.^{5,21} Cirrhosis develops gradually in about 20-30% of CHC patients, over the course of roughly 25-30 years.^{5,21} In addition, cirrhosis increases risks of both clinical decompensation and HCC development, which have yearly rates of 2-5% and 1-4%, respectively, and may lead to end-stage-liver disease (ESLD), need for liver transplantation, or death.^{5,21} Research has suggested HCV infections may cause extrahepatic manifestations (EHMs) affecting the skin,

eyes, thyroid, kidneys, joints, immune system, and nervous system and may increase rates of morbidity and all-cause-mortality.^{28,31} Allowing HCV to progress through this natural course of disease and suffering leads to significant social and economic costs.

Unlike hepatitis B or human immunodeficiency virus (HIV), there is no vaccine or post-exposure prophylaxis for hepatitis C, but a cure is available through treatment with DAAs.⁴ According to *HCV Guidance* from the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA),²⁸ the “goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.” DAAs offer tolerable 8-12 week oral treatment regimens as a highly-effective means to cure HCV in more than 90% of patients; however, in the U.S. their high cost of around \$1000 per pill and over \$80,000 per standard treatment course has been limiting their use and impact on the burden of hepatitis C.^{17,28,32,33} In the U.S., estimates suggest only 5-6% of persons with HCV have successfully completed treatment, and cost is among factors limiting treatment uptake.^{34,35} Potential health benefits of SVR include decreased liver inflammation, slowed progression of liver fibrosis, resolution of cirrhosis, improvement of extrahepatic and advanced liver disease clinical manifestations, and reduced risks of HCC by more than 70% and liver-related mortality and liver transplantation by 90%.²⁸ Furthermore, the AASLD and IDSA²⁸ report, “Persons who have successfully achieved an SVR (virologic cure) no longer transmit the virus to others.” As a result, the rising burden of HCV is prompting serious consideration of the benefits and cost-effectiveness of treatment to reduce HCV transmission, especially among high risk populations such as PWID and incarcerated individuals.^{17,28}

Theory and Previous Research

Epidemiology and Interrelated Epidemics in the United States and Kentucky

In the U.S., HCV has been growing as a hidden high-risk threat to the health of the nation.⁶ Although the true prevalence of HCV in the U.S. is unknown, research to ascertain more accurate approximations has suggested at least 3.5 million persons may be currently infected with HCV out of an estimated 4.6 million persons with HCV-antibodies (anti-HCV), indicative of past or present HCV infection.³⁴ More recently, 2010 U.S. anti-HCV prevalence was estimated to be about 1.67% or 3,911,800 adults.³⁶ According to Centers for Disease Control and Prevention (CDC) surveillance data, reported cases of acute HCV infection have risen yearly from 2010 through 2015, increasing more than 2.9-fold during that 5-year period.⁹ In 2015, there were 181,871 cases of confirmed past or present hepatitis C infection newly reported from 40 states and an estimated 33,900 new HCV infections, after adjusting for under-ascertainment and under-reporting.⁹ From 2011-2014, HCV-related deaths rose by 10.9% but declined slightly by a 0.2% in 2015 to 19,629; however, HCV is known to be underestimated and underreported on death certificates.⁹ The persistent rise of acute hepatitis C infections in recent years has been described as HCV transmission epidemics, particularly among young white persons in nonurban areas and Appalachia, as a consequence of the opioid epidemic and its shift from oral to IDU and abuse of prescription opioids and heroin.^{6,9}

As a state in the Appalachian region, Kentucky is among states most devastated by the inseparable opioid and HCV epidemics. Kentucky's *State Health Assessment 2017 Update* revealed opioid overdose deaths tripled from 2006-2015 and 1,089 new cases of acute HCV infection from 2008-2015, making Kentucky the state with the highest rate of acute HCV in the

U.S.¹⁴ Recent research estimated Kentucky's 2010 anti-HCV prevalence to be approximately 1.63% with 54,200 persons with past or present hepatitis C infection at that time.³⁶

In response to Indiana's 2014-2015 Austin, Scott County outbreak of HIV infections within a network of PWID, 92% of whom had HIV-HCV coinfections, Van Handel and colleagues performed *County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States*, which found Kentucky to be among the most vulnerable states with 54 of its 120 (45%) counties and 24.5% of the 220 U.S. counties considered vulnerable.³⁷ Such research highlights additional threats posed by these related epidemics, illuminating the need to explore potential opportunities for multidisciplinary interventions where these epidemics intersect at national, state, county, community, and individual levels.

Corrections and the Hepatitis C and Substance Use Disorder Epidemics

The U.S. has also been described as having an "incarceration epidemic" with the number of U.S. prisoners more than tripling from 585,084 in 1987 to 1,596,127 in 2007.^{1,18} Furthermore, the epidemics of hepatitis C and SUD intersect in U.S. corrections systems and populations to such an extent that corrections settings warrant serious consideration of applicable interventions. Federal jails and prisons, local jails, and state prisons make up major component subsystems of the corrections network, and each subsystem houses populations of legal offenders, based on types of crimes committed.^{38,39} Local jails and state prisons serve similar populations of offenders that have committed nonviolent (e.g., theft, drug possession, prostitution) and/or violent (e.g., rape, murder) types of crimes.³⁸ Arrested offenders usually have a short length of stay in local jails before adjudication and afterwards if their sentence is 1 year or less.^{38,39} Once convicted of felonies or sentenced to long-term confinement for more than 1 year, inmates are

incarcerated in state prisons.^{38,39} Federal jail and prison systems are similar but serve those who have committed federal crimes, including mail fraud, tax evasion, bank robbery, and kidnaping, among others.³⁸ These correctional systems form the structure of this key intersection of the U.S. opioid and hepatitis C epidemics.

Further definition of this intersection and its importance is accomplished through dissection of the populations within these systems. Figure 1 displays division of the total U.S. and Kentucky incarcerated populations into selected sub-populations.^{39,40}

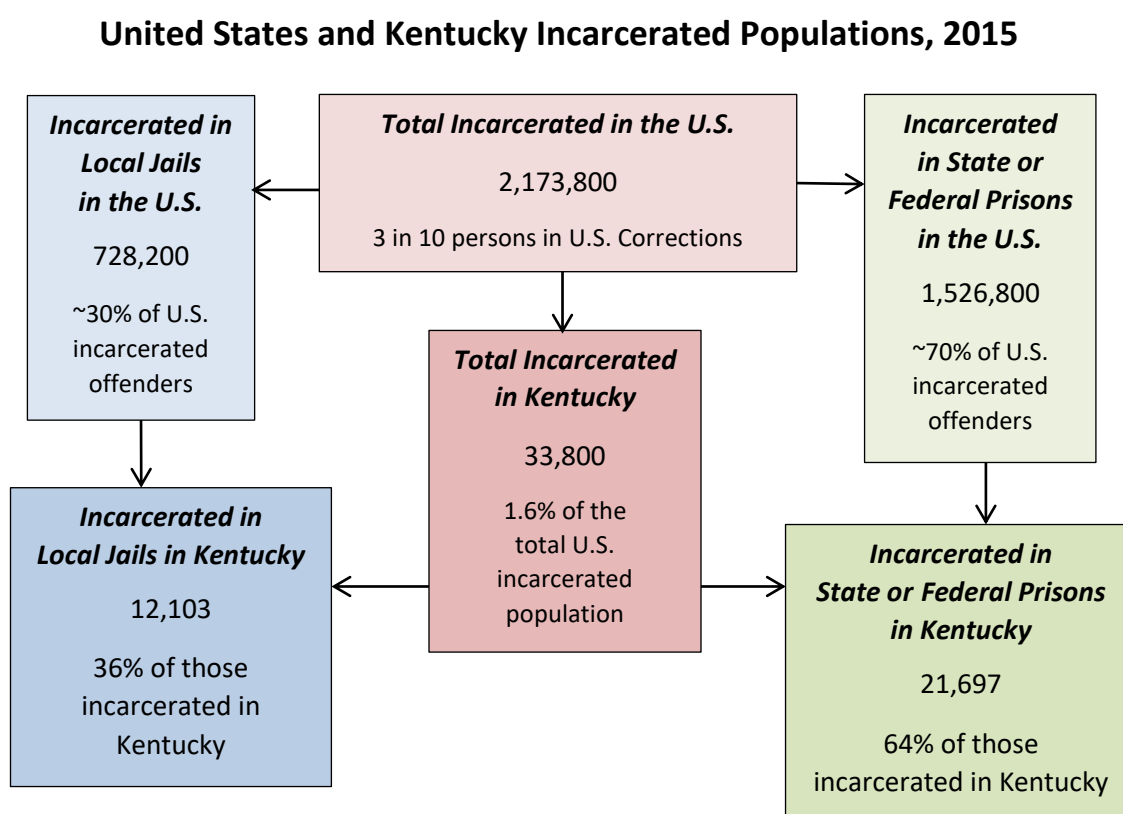


Figure 1: A diagrammatic representation of the 2015 yearend total U.S. and Kentucky incarcerated populations broken down into their respective sub-populations, which include those incarcerated in state or federal prisons, local jails, and others not listed here. Bureau of Justice Statistics 2015 yearend count data^{10,11} along with additional available reported statistics and calculated percentages are presented.

Prisoners not only make up the majority of incarcerated individuals, as seen above, but there are several reasons they may also be an imperative intervention target population. For

instance, not surprisingly, prison populations have a high prevalence of both IDU and HCV. Some estimates of history of IDU among inmates range from 20% - 55%.¹⁷ In Kentucky, offenders self-reported heroin use rose from 7.4% (N=1,756) in FY2007 to 28.9% (N=5,782) in FY2016 and 44.0% self-reported illicit opioid use (excluding heroin, methadone, buprenorphine) in FY2016.⁴¹

Most recent HCV seroprevalence estimates applicable to U.S. prisoners range from approximately 17% - 30%, suggesting around 500,000 to over 1 million incarcerated individuals may be infected.^{34,42,43} In contrast, the U.S. noninstitutionalized population has an estimated anti-HCV seroprevalence 1.67%.³⁶ With both hepatitis C and IDU common among prisoners, upon their eventual release back into society, HCV infected prisoners, especially those with history of IDU, may spread hepatitis C to members of the general population in the community.^{17,44} As a result, incarcerated populations have been recognized as an important population to consider targeting with multidisciplinary interventions to curb these interrelated epidemics.

Prisoners are also set apart from other possible target populations as the only population in the U.S. with a constitutional right to healthcare, protected by the Eighth Amendment's prohibition of cruel and unusual punishment.^{19,38} The following three basic rights were guaranteed as a result of the 1976 U.S. Supreme Court landmark case *Estelle vs. Gamble*: to access care, to receive the care ordered, and to obtain professional medical judgement.³⁸ Claims of "deliberate indifference" to prisoners' serious health needs may be filed and tried in federal court if these rights are violated.³⁸ Failure of state prisons to provide the costly but highly curative DAAs to prisoners with known HCV has led to class-action lawsuits against Departments of Corrections in several states, including Minnesota, Pennsylvania, and

Massachusetts; an individual prisoner's lawsuit against the Pennsylvania DOC resulted in a court order requiring the DOC's provision of treatment.^{24,45,46}

Prisoners are the center of the triad of epidemics, and among those infected with HCV they are at great risk spreading it in correctional settings and in the community upon release, making them a potentially imperative component to addressing these public health crises. The research of He and colleagues via an agent-based microsimulation model of HCV transmission and progression suggested risk-based and opt-out HCV screening in U.S. prisons during the next 30 years could potentially diagnose 41,900-122,700 new cases of hepatitis C and prevent 5,500-12,700 new HCV infections and 4,200-11,700 liver-related deaths by treating HCV-infected prisoners prior to release.¹⁷ In the research simulation, 89-92% of prevented HCV infections and 80% of liver-related deaths would have occurred in the community outside prison.¹⁷ Thus, research suggests universal opt-out HCV screening of prisoners with treatment to cure hepatitis C infections prior to their release could be a form of primary prevention of HCV transmission and new infections in the general community.¹⁷

Hepatitis C Screening and Treatment of Prisoners – Guidelines and Policy

Various recommendations and guidelines advocate for the provision of hepatitis C services, including screening and treatment, in incarcerated populations. In 2010, the Institute of Medicine (IOM)^{7,47} published *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, a consensus study report that included the following recommendation for correctional settings: "Recommendation 5-8. The Centers for Disease Control and Prevention and the Department of Justice should create an initiative to foster partnerships between health departments and corrections systems to ensure the availability of comprehensive viral hepatitis services for incarcerated people." For hepatitis C, the IOM

defined minimum services for all incarcerated individuals to include offering HCV screening and testing, providing educational programs with peer education and emphasis on hepatitis C, and developing systems to ensure continuity of medical care for HCV infections upon release from incarceration.⁷

The 2011-2013 advent of DAAs transformed HCV treatment approaches and effectiveness, compelling both the CDC and the U.S. Preventive Services Task Force (USPSTF) to update and expand their recommendations for HCV screening and treatment in 2012 and 2013, respectively.^{27,29,32,48} The CDC, USPSTF, AASLD and IDSA recommend one-time screening of 1945-1965 birth cohort members because they have a higher likelihood of HCV infection, probably secondary to receipt of blood transfusions prior to screening of blood products in 1992 or history of other exposure related risk factors.^{28,29,48} Although the USPSTF updated recommendations list past or current IDU as the most important risk factor, incarceration is also a risk factor warranting HCV screening.²⁹ The WHO's most recent HCV guidelines recommend screening of PWID and "prisoners and previously incarcerated persons" as well.²⁶ HCV guidance from the AASLD and IDSA recommends one-time HCV screening for all persons who have ever engaged in IDU, even once, and/or have ever been incarcerated along with annual HCV testing for PWID.²⁸ Moreover, since at least 2003, the American Society of Addiction Medicine (ASAM) has recommended offering voluntary serologic HCV testing to persons with history of IDU.⁴⁹ Evidence-based hepatitis C guidelines and recommendations consistently list IDU and incarceration as risk factors necessitating HCV screening.

The Federal Bureau of Prisons (BOP) provides clinical practice guidelines (CPGs) for management of infectious diseases in correctional facilities, to fulfill objectives of the Correctional Officers Health and Safety Act of 1998.⁵⁰ The CPGs include the BOP Clinical

Guidance on *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection* for the federal inmate population, but these recommendations are important considerations for state inmate populations as well.⁵¹ The BOP-recommended modified test-and-treat strategy for HCV infection consists of the following five steps⁵¹:

- STEP 1: Test for HCV infection with anti-HCV (HCV Ab) test.
- STEP 2: Perform a baseline evaluation of inmates who are anti-HCV positive.
- STEP 3: Assess for hepatic cirrhosis/compensation and BOP priority criteria for treatment, if HCV RNA is detectable.
- STEP 4: Perform a pretreatment assessment, if priority criteria for treatment are met.
- STEP 5: Monitor patient during and after treatment.

Pertinent aspects of these BOP HCV CPGs and steps will be further discussed below.

For Step 1, the BOP recommends screening for HCV infection in all sentenced inmates, all inmates with certain clinical conditions (e.g. reported history of HCV without medical documentation, chronic hemodialysis (HD), elevated alanine aminotransferase (ALT) of unknown etiology, evidence of extrahepatic HCV), and all inmates who request testing.⁵¹ Due to higher prevalence and risk of HCV infection in incarcerated populations, the Federal Bureau of Prisons (BOP) recommends opt-out, informed refusal, voluntary HCV screening of all sentenced inmates at the prevention baseline healthcare visit.⁵¹ Hepatitis C screening begins with serologic testing for anti-HCV antibodies.^{28,29,48,51,52} A positive anti-HCV test result may indicate current (active) acute or chronic HCV infection, past resolved infection, or a false-positive test result; so, it must be followed by confirmatory testing with a sensitive HCV nucleic acid test (NAT), also known as an HCV RNA (ribonucleic acid) test, to assess viremia and distinguish between those possibilities.^{28,29,48,51,52}

Step 2 of the BOP recommendations applies to all inmates with positive anti-HCV screening results and consists of a baseline clinical evaluation with a targeted history and physical examination (H&P) and laboratory testing, including confirmatory “[q]uantitative HCV

RNA viral load testing, sensitive to ≤ 25 IU/ml, with reflex testing for HCV genotype, to determine if the inmate has active HCV infection and identify the HCV genotype.”⁵¹

Confirmatory testing in which HCV RNA is detected is interpreted as current (active) acute or chronic HCV infection whereas undetectable HCV RNA indicates resolved past HCV infection or false-positive anti-HCV test.^{28,29,48,51,52} BOP Steps 3-5 describe management recommendations for those diagnosed with active HCV infection.⁵¹

When DAAs were newly available, the AASLD and IDSA joint expert panel recommendations included treatment prioritization tables, responding to the combination of limited knowledge of medication safety and tolerability in real world populations and inadequate infrastructure to readily treat all HCV infected patients.²⁸ Since then, experience and evidence of the clinical benefits of virologic cure have led the AASLD and IDSA²⁸ to eliminate prioritization tables and update their *Recommendation for When and Whom to Initiate Treatment* as follows: “Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.” The AASLD and IDSA guidance also highlights potential benefits of treatment both at earlier fibrosis stages (below Metavir Stage F2) and to reduce transmission by achieving SVR in populations at highest risk for transmission such as PWID and incarcerated individuals.²⁸

The BOP acknowledges that “all patients with chronic HCV infection may benefit from treatment” but continues to recommend assessment of *BOP Priority Criteria for Treatment* as “an important part of the initial evaluation and ongoing management of inmates with chronic

HCV infection” (see Appendix, pgs. 58-59).⁵¹ The BOP is not alone in its decision to retain treatment prioritization in its recommendations for reasons discussed later in this paper.

Hepatitis C Screening and Treatment of Prisoners – Implementation and Practice

The *National Survey of Prison Health Care (NSOPHC)* targeted all 50 state DOCs and the BOP with semi-structured telephone interviews in 2012, to collect 2011 calendar year data about U.S. prison healthcare, and revealed notable variation in prison admissions’ HCV screening practices with few states implementing the BOP recommended opt-out screening strategy.⁵³ Of the 45 states that participated in the survey, 36 states, including Kentucky, tested at least some incoming prisoners for HCV.⁵³ Some state respondents voluntarily disclosed additional details about their approaches to HCV testing of incoming prisoners, which included universal testing in 3 states versus testing upon clinical indication in 23 states and opt-out testing in 5 states versus opt-in testing in 2 states.⁵³

The American Correctional Association (ACA) and the Coalition of Correctional Health Authorities (CCHA) Research and Health Outcomes working group performed research about HCV infection management in corrections in the summer of 2014, through their survey of 57 CCHA members, including representatives from all 50 state DOCs, 6 large U.S. jail systems, and the BOP.⁵⁴ There were 51 responses to agency-type questions from 3 (6%) jails, 41 (81%) prisons, and 7 (14%) unified systems (jails and prisons managed by one agency). At the time of the survey, respondents provided the following information about timing and indications of HCV screening: 10% (5 respondents) were not performing HCV testing and the other 90% (45 systems) were testing according to defined criteria, such as physician request (90%, 44 systems), identified risk factors and inmate request (both 69%, 34 systems).⁵⁴ All offenders were being screened on admission at 8 (16%) of the responding facilities. Diagnostic testing performed to

identify cases of HCV consisted of anti-HCV positivity alone at 23 (47%) facilities versus both the former test plus evidence of viremia at 34 (70%) of the facilities.⁵⁴ The research report did not divulge the identities of states or systems that responded, so Kentucky specific information could not be ascertained from this study.

Estimates of hepatitis C prevalence among incarcerated populations are limited and variable as a result of differences in HCV screening policy and practice among nations and states. True prevalence estimates are the most accurate because they identify all HCV cases of infection by screening all inmates such as on admission and comparing results to the average daily census.⁵⁴ On the other hand, diagnosed prevalence uses only known identified HCV cases as a percentage of the average daily population, making less accurate estimation possible in settings where not all inmates are tested, but it is not equivalent to and may underestimate true disease prevalence in a population.⁵⁴

North America's incarcerated population has an estimated anti-HCV seroprevalence of 29% (95% CI range 24%-34%) and about 668,500 (range: 553,500-784,000) infected inmates, according to results from Larney and colleagues 2013 systematic review and meta-analysis, which used 14 studies (5 Canada and 9 U.S.) with convenience sample seroprevalence data from new entrants and/or current detainees from 1985 to 2004.⁴² After surveying all state Departments of Corrections in the U.S. and receiving 2001 to 2012 anti-HCV seroprevalence data from routine testing in 12 states, Varan et al. estimated both the 2006 U.S. median hepatitis C seroprevalence among state prisoners at 17.4% (range: 9.6%-41.1%) and the correctional populations' proportion of 2006 total U.S. hepatitis C cases from 28.5%-32.8%.⁴³

The ACA and CCHA 2014 survey results include both true prevalence and diagnosed prevalence estimates.⁵⁴ True prevalence was estimated using HCV prevalence data, ranging

from 8%-17%, from the 12 months prior to the study from 7 systems that screen all inmates on admission; the calculated true seroprevalence was 11.6% (22,907 infected individuals/197,720 total offender population represented). Diagnosed prevalence data provided by 31 correctional systems (# of facilities with diagnosed prevalence %: 19 with <10%, 11 with 10-20%, 1 with >20%) was used to calculate an estimate of 8.7% (88,647 infected individuals/197,720 total offender population represented). The approximate hepatitis C case burden, number of known cases among the correctional systems surveyed, was determined to be 109,554 by combining the cases from both the true and diagnosed prevalence groups; however, this is likely a gross underestimation of the true HCV burden in U.S. Corrections, since so few facilities screen their entire incarcerated populations.⁵⁴

The systematic review and analysis of Edlin et al.³⁴ used 22 studies (from 1994-2013 with data mainly from state prison systems but 5 included data from local jails) reporting HCV seroprevalence among incarcerated individuals in 23 states to estimate both a weighted mean prevalence of 23.1% (95% CI range 7.5%-44.0%) and 505,350 (range: 163,967-961,941) infected persons within the U.S. incarcerated population.³⁴

Despite the impact the opioid and hepatitis C epidemics are having on the state of Kentucky, relevant information about Kentucky prisoners is lacking. For instance, Kentucky was not among the known states with available data used to estimate HCV seroprevalence in incarcerated populations in the above studies.^{34,42,43} The relative absence of HCV seroprevalence data from Kentucky correctional populations in the published literature may be due to limited screening and treatment practices. However, two sources with Kentucky specific data were identified. At the 2014 Kentucky Conference of Viral Hepatitis, Dr. Kraig Humbaugh, Senior Deputy Commissioner and Director of the Division of Epidemiology and Health Planning,

Kentucky Department for Public Health (KDPH), presented 2010-2013 data from the KDOC, which is available on the KDPH website and included and further analyzed here in Table 3.

More recently, Beckman and colleagues cross sectional study presented state level data of the numbers of diagnosed HCV cases and treatment recipients in state prison systems, including Kentucky.³³ The researchers distributed online survey questionnaires to the commissioners of all 50 state DOCs in 2 phases (module 1 in February 2015 and module 2 in October 2015) to assess their current hepatitis C healthcare practices; 49 states, excluding Maine, responded to module 1, 31 (63%) of which also completed module 2. Of the 41 states (84%) that provided HCV infection and treatment data, 17 states (35%) were practicing routine opt-out HCV testing, whereas, Kentucky and 31 other states (65%) were not. Most common indications for HCV testing in the latter group were other abnormal test results (29 states), HIV (27 states), or SUD (16 states).³³ On or around January 1, 2015 in the 41 reporting states, a total of 106,266 prisoners (10%) had diagnosed acute or chronic hepatitis C infections but only 949 (0.89%) were receiving treatment. State proportions of HCV infected prisoners ranged from 1% to 41% in North Carolina (n=220) and New Mexico (n=2,850), respectively (median 10% with interquartile range [IQR] 8%-13%), and Kentucky (n=1,631) was among 10 states with 8.75%-11.5% of their prisoners infected with hepatitis C.³³ As expected, states' treatment uptake was variable with the proportion of known HCV infected prisoner receiving treatment ranging from 0.0% in 4 states to 5.9% in New York (median 0.45% with IQR 0.12%-1.48%). Treating 0.12% (n=2) of HCV infected prisoners, Kentucky was one of 27 states (66%) offering treatment to less than 1% of prisoners with known HCV infections.³³ States reported using the following criteria, listed from most commonly reported to least commonly reported, to prioritize treatment of hepatitis C infected prisoners: remaining length of sentence (44 states), cirrhosis (41 states), comorbidities,

liver failure, CHC (23 states), HCC, chance of reinfection (12 states), acute HCV, chance of recidivism (5 states), and exposure to HCV. States' "other" self-explained criteria included: "prisoner's compliance for treatment for drug use, alcohol abuse, or both" (5 states); mental health conditions (3 states); assessment of liver fibrosis and cirrhosis via the aspartate aminotransferase to platelet ratio index (APRI) (10 states); and "followed all of the Federal Bureau of Prisons guidelines" (4 states).³³ In survey module 1, 44 states (90%) reported attempting to obtain DAAs (sofosbuvir and ledipasvir/sofosbuvir [Havroni]) below U.S. list price, using various strategies, such as the following: "direct negotiations with pharmaceutical companies" (29 states, 66%); federal 340B Drug Discount Program (16 states, 36%); pooled procurement (13 states, 30%); discounts via the Minnesota Multistate Contracting Alliance for Pharmacy (5 states, 9%).³³ In module 2, several states provided financial data on DAA costs as of September 30, 2015, but Kentucky was not among them. A 12-week course of sofosbuvir costed state prison systems from \$43,418 in Connecticut to \$84,000 in Michigan with a median price of \$76,084.50; a few states with the lowest prices were using the 340B Drug Discount Program. The median price for a ledipasvir/sofosbuvir treatment regimen was \$63,509.³³ Unfortunately, since much of the data from this study is presented in aggregate categories, little Kentucky specific information could be filtered from it. Yet, Beckman and colleagues research yielded a wealth of valuable information, illuminating the extent of which hepatitis C treatment costs appear to be hindering the ability of state DOC to screen and treat their prison populations.

The high cost of DAA regimens is forcing HCV treatment prioritization in the setting of payer budget constraints, not only impacting state DOCs but Medicare and Medicaid as well. For example, many state Medicaid programs have developed prior authorization criteria for sofosbuvir, a commonly recommended DAA, limiting treatment coverage eligibility and

associated costs, and Kentucky is among those states.^{28,32} Kentucky Medicaid's actual expenditures were over \$6.9 billion in 2014 and over \$9.5 billion in 2015.⁵⁵ Currently, treating one HCV infected patient with DAAs costs Kentucky Medicaid \$83,735.⁵⁶ According to Liao and colleagues, Kentucky has strict clinical, administrative, and behavioral criteria for sofosbuvir HCV treatment utilization, and 0.66% of Kentucky Medicaid fee-for-service drug spending was used for coverage of that medication in 2014.³² More specifically, Kentucky Medicaid restricts sofosbuvir reimbursement to HCV infected beneficiaries with METAVIR fibrosis stage F3 or higher and requires a 6 month period of abstinence from drugs and alcohol.^{32,57} The ethics and legality of such treatment prioritization and restrictions among Medicaid recipients and prisoners are being questioned.^{32,33}

Despite marked variation in HCV management in U.S. correctional populations, recent research supports HCV screening and treatment of hepatitis C infected prisoners as a cost-effective strategy capable of reducing HCV transmission, infections, and complications, particularly in the U.S. community at large, rendering it among conceivable options to address the HCV epidemic in the U.S. and Kentucky.^{17,33,58,59}

Literature Summary and Conclusion

Following this triad of epidemics through its historic course in the U.S. reveals Kentucky has been particularly affected from the outset and continues to be profoundly impacted by all three. Similarly, in both the past and present, HCV treatment costs have been among the challenges making the hepatitis C epidemic impossible to control and indirectly facilitating its spread in correctional settings, the general community, states, and the nation. In 2000, the KDOC was involved in the first prisoner lawsuit over hepatitis C treatment and was court ordered to provide treatment after previous denial. Prisoners are a marginalized and underserved

population with a constitutional right to healthcare that only mandates meeting minimum standards, resulting in variable implementation of guideline recommendations, including HCV screening and treatment.^{19,53} Collectively, the incarceration, opioid, and hepatitis C epidemics make balancing constrained U.S. federal and state government budgets even more challenging, especially when attempting to factor in the expense of HCV treatment regimens. PWID and incarcerated populations are at greatest risk of increasing HCV transmission and incidence both inside correctional settings and outside in the community, but they are often restricted from access to DAAs, even though achieving SVR could prevent them from infecting others with HCV.^{10,17,28,32,33,51} With the opioid epidemic and IDU as primary drivers of the hepatitis C epidemic, targeting U.S. incarcerated populations with multidisciplinary interventions, including treatment of both HCV infections and SUDs, may powerfully address both escalating epidemics simultaneously.

As a result, research has been expanding in these areas to further define the burden of HCV in U.S. incarcerated populations and to assess current HCV management practices in U.S. corrections.^{33,53,54} Even though this triad of epidemics is devastating Kentucky, information and research focusing primarily on hepatitis C in incarcerated populations in Kentucky is lacking. The HCV burden among Kentucky prisoners is unknown, likely secondary to limited screening and inadequate surveillance. Minimal information gleaned from previous nationwide studies indicates, as of early 2015, KDOC was not performing routine opt-out HCV testing, and its proportion of state inmates receiving HCV treatment was nearly zero. Taking a closer look at hepatitis C among prisoners in Kentucky, this study aims to begin examination of pertinent policy, practice, and economic factors that may redefine this stigmatized population as not only contributors to rampant spread of hepatitis C but also a key to containing the epidemic.

METHODS

A combination of research methods was employed to examine HCV screening and treatment policy and practice applicable to Kentucky prisoners, as described below in the following subsections:

Literature Search and Analysis

Kentucky Department of Corrections – Hepatitis C Policies and Procedures

Kentucky Demographics – General Population and Prisoners

Seroprevalence Estimates and the Burden of Hepatitis C in Kentucky

Hepatitis C Screening and Treatment in Kentucky State Prisons, 2010 to 2013

Estimated Costs of Hepatitis C Screening and Treatment in Kentucky Prison Populations

Consideration of Costs of Failing to Treat Prisoners Prior to Release

Collectively, these methods helped to identify relevant policy and practice to consider Kentucky prisoners as a potential target for multidisciplinary interventions to combat the SUD and hepatitis C epidemics and prevent HCV transmission.

Literature Search and Analysis

This research was based primarily on relevant publicly available scholarly and grey literature, and data sources, which were identified as described in the *Literature Review – Introduction* above, to establish a foundation on the subject matter of interest. Data analysis was performed via Microsoft Excel 2016 and manual calculations.

Kentucky Department of Corrections – Hepatitis C Policies and Procedures

In addition to BOP guidelines, previously discussed, the search for policies and procedures about HCV screening and treatment of Kentucky prisoners led to the KDOC *Medical and Health Care Services Policies and Procedures* webpages, where *13.2 Health Maintenance Services* and *13.10 Serious Infectious Disease* were identified as the relevant accessible sources.^{60,61}

Kentucky Demographics – General Population and Prisoners

U.S. Census Bureau⁶² data from 2010 and Bureau of Justice Statistics (BJS), National Prisoner Statistics Program⁴⁰ data from 2015 were used as sources for total population counts of both the Commonwealth of Kentucky's general population and prison population (federal and state prison populations combined) as well as demographic information for stratification by age, sex, and ethnicity. The population data, including proportions calculated as percentages, is provided in Table 1. Although the demographic make-up of Kentucky's 2015 populations will likely be somewhat different from that of 2010, since this data was the most recent of both populations, it was assumed that the populations were acceptably comparable for the purposes of gross observation performed here.

The Prevalence and Burden of Hepatitis C Virus in Kentucky

The best available data and estimates from the literature were used to better understand the prevalence and burden of hepatitis C among noninstitutionalized adults and prisoners in Kentucky, as presented in Table 2. Recent research by Rosenberg and colleagues³⁶ determined 2010 state-level anti-HCV prevalence estimates among noninstitutionalized persons 18 years of age and older, using data from the U.S. National Health and Nutrition Examination Survey (NHANES), National Vital Statistics System (1999-2012), and Census Bureau (2010); their estimates of the HCV prevalence and number of infected persons among non-institutionalized adults in Kentucky served as the source of that information in Table 2. Anti-HCV seroprevalence estimates in Kentucky prisoners were not found in the literature. As a result, systematic reviews and meta-analyses^{34,42,43} that yielded anti-HCV seroprevalence estimates applicable to U.S. prison populations were used as references, assuming they were not significantly different from Kentucky prison populations, along with 2015 Bureau of Justice

Statistics (BJS), National Prisoner Statistics Program⁴⁰ data to calculate estimates with 95% CIs of the number of infected persons among Kentucky state and federal prisoners, admissions, and releases (see Table 2). Later, 2010-2013 Kentucky Department of Corrections' (KDOC) data was discovered from Humbaugh⁶³ (see Table 3) amidst grey literature and used to calculate a sample mean with 95% CI of confirmed HCV prevalence among Kentucky state prisoners, which was then used to estimate the number of infected Kentucky prisoners, as previously performed with the other reference estimates (see Table 2). With Kentucky's absence among the reference populations^{34,42,43} but inadequate Kentucky data⁶³ to estimate its true HCV population prevalence, it was assumed that the 4 estimates were adequately comparable to obtain their means and 95% CIs as an attempt to better approximate the possible hepatitis C prevalence and burden among Kentucky state and federal prisoners, admissions, and releases (see Table 2). Beckman and colleagues 2015 data about hepatitis C infections among Kentucky state prisoners was excluded from was excluded from the Table 2 because it was discovered after completion of the analysis, less information was known the sample versus Humbaugh's samples, and some prisoners might be represented in both samples.^{33,63}

Hepatitis C Screening and Treatment in Kentucky State Prisons, 2010 to 2013

The publicly available Kentucky Department of Corrections' (KDOC) data from Humbaugh's presentation⁶³ included the number of inmates in Kentucky state prisons each year from 2010-2013, who received HCV screening and positive confirmatory testing, and initiated treatment. This research included further analysis of that data, including calculation of proportions (%) of those screened who were confirmed HCV positive and of those positive who started HCV treatment as well as both the number and proportion of untreated HCV positive inmates, and the means and medians of each category (see Table 3). A graphical representation

of this information is presented in Figure 2. Also, the most recent Kentucky Medicaid estimate for average cost of \$83,735 to treat one HCV patient was used to estimate current costs to treat those left untreated.⁵⁶ Smaller discounts, exclusion from rebates, and lack of leverage for price negotiations may force state correctional systems to pay higher prices for hepatitis C treatment regimens than other organizations, including Medicaid.^{28,33} Consequently, based on the assumption that KDOC's price for DAAs was unlikely to be less than that of Kentucky Medicaid, the current average per patient treatment cost of Kentucky Medicaid was used as the per prisoner HCV treatment cost estimate for KDOC.

Costs of Hepatitis C Screening and Treatment in Kentucky Prisoners

First, costs to screen and treat all Kentucky state and federal prisoners, admissions, and releases were estimated with results presented in Table 4. The total number of prisoners (yearend counts from December 31, 2015), admissions, and releases from the 2015 Bureau of Justice Statistics (BJS), National Prisoner Statistics Program were assumed to be similar enough to those in 2017 to use for calculation of 2017 cost estimates.⁴⁰ The estimated numbers and 95% CIs of infected prisoners, admissions, and releases from Table 2 were also used to estimate costs. Screening was assumed to be 100% sensitive and 100% specific, resulting in successful diagnosis of all cases of HCV infection.¹⁷ Kentucky Medicaid costs from 2017 were used to estimate costs for screening and treatment, including consideration of scenarios in which the costs to treat one HCV infected patient were discounted by 25% and 50%.^{50,56} Calculated cost estimates were also compared to Kentucky enacted FY2017 budgets, specifically the \$57,086,000 KDOC medical services budget and the \$10,578,419,600 Kentucky Medicaid Services benefits budget (see Figures 3 and 4).⁶⁴ On December 31, 2015, 11,987 Kentucky state prisoners made up 55% of the total 21,701 Kentucky state and federal prisoners.^{40,65} Assuming

HCV cases are proportionately distributed between state and federal prisoners, state prisoner cost estimates and 95% CIs were calculated as 55% of Kentucky prisoners' cost estimates from Table 4 along with corresponding proportions and 95% CIs of the KDOC medical services budget they would consume (see Figure 3). HCV screening and treatment cost estimates for Kentucky prison releases from Table 4 were used to estimate percentages of the Kentucky Medicaid Services benefits budget they would require (see Figure 4).

Consideration of Costs of Failing to Treat Prisoners Prior to Release

A rather rudimentary analysis of a hypothetical transmission scenario was performed, considering potential secondary costs of failure to treat prisoners prior to release if the known infected but untreated Kentucky state prisoners (n=1,030 from 2010-2013 in Table 3) each infected at least 1 person in the community upon release, resulting in at least 1,030 new cases of HCV in the community. Assuming the natural history stages of hepatitis C infection occurred among the new community cases in accordance with the proportions previously listed in the "Overview of Hepatitis C" section, those proportions served as references to estimate the number of new cases impacted by each HCV stage.^{4,5,21} Using reference costs of one-time screening outside prisons at \$2,873^{17,66} and the Kentucky Medicaid⁵⁶ average cost of \$83,735 to treat one HCV infected patient, the following cost estimates were calculated: screening all cases, treating all cases, and only treating CHC patients. Results are presented in Table 5.

Last, potential healthcare costs of failing to treat HCV in these populations of interest were estimated using a reference estimate of \$100,000 average lifetime healthcare cost for hepatitis C per patient, excluding liver transplantation.⁶⁷ Of note, these HCV lifetime healthcare cost estimates did not account for the time value of money through the use of discount rates and cannot be directly compared to current screening and treatment cost estimates, as a result.

RESULTS

The results necessary for foundational examination of HCV screening and treatment policy and practice pertaining to Kentucky prisoners are reported below in subsections mirroring their corresponding methods subsections, which include:

Kentucky Department of Corrections – Hepatitis C Policies and Procedures
Kentucky Demographics – General Population and Prisoners
The Prevalence and Burden of Hepatitis C Virus in Kentucky
Hepatitis C Screening and Treatment in Kentucky State Prisons, 2010 to 2013
Costs of Hepatitis C Screening and Treatment in Kentucky Prison Populations
Consideration of Costs of Failing to Treat Prisoners Prior to Release

Each subsection provides important information for analysis and consideration, regarding the role Kentucky prisoners may play among solutions to the triad of epidemics with particular focus on hepatitis C.

Kentucky Department of Corrections – Hepatitis C Policies and Procedures

Aspects of the KDOC *Medical and Health Care Services Policies and Procedures*^{*} that pertain to HCV management among prisoners, specifically *13.2 Health Maintenance Services* and *13.10 Serious Infectious Disease*, are discussed in this section.^{60,61} Regarding implementation, the KDOC *Serious Infectious Disease*⁶⁰ policy and procedure states, “All procedures shall conform to current standards of medical practice and take into consideration established guidelines and recommendations from”:

- (a) The Center for Disease Control and Prevention (CDC);
- (b) The CDC’s Advisory Committee for Immunization Practices (ACIP);
- (c) The Occupational Safety and Health Administration (OSHA);
- (d) The National Institutes for Occupational Safety and Health (NIOSH); and
- (e) The Department of Health and Human Services (DHHS).

^{*} “The Policies and Procedures provided at this Web site are unofficial versions and are intended for informational purposes only. They are provided by the Department as a service to the public. They are subject to change at any time and do not include the secured Policies and Procedures of the Department. The Department does not guarantee the accuracy or completeness of the postings.”^{61,62}

With respect to disease prevention the policy and procedure explains, “Serious infectious disease and health risks leading to disease may be identified by various means including health screening, risk assessment, physical examination, laboratory report, personal history, injury report and training and education.”⁶⁰

Upon admission intake to Kentucky Corrections, all inmates receive an initial evaluation, which includes the following: information about serious infectious diseases; completion of a screening form and interview to identify the presence or risk of health problems and serious infectious diseases; health history within 48 hours after admission; and physical examination including TB skin testing and “venereal disease” testing within 10 working days.^{60,61} The *Serious Infectious Disease*⁶⁰ Assessment explains, “If an inmate is suspected of being in a situation involving a high risk of exposure to a serious infectious disease, he shall submit to testing deemed necessary by the appropriate medical staff [...]” According to the *Health Maintenance Services* policy and procedure, the primary care provider’s intake examination and determination of medical status are used to develop the total incarceration plan for medical care and physical activity.⁶¹ The following excerpt from the health category classification review also appears to apply to hepatitis C⁶¹:

- b. If a health problem is present on admission that, if left untreated, may cause deterioration of the inmate's general health or result in permanent disability: [...]
 - 2) The care or services needed to maintain, at a minimum, the present level of health shall be provided within the institution.

The KDOC “Receiving Screening Form” has two questions more specifically related to hepatitis, one asking about jaundice and another directly asking the inmate, “Do you have hepatitis?” (see Appendix, pgs.60-62).⁶¹

Kentucky Demographics – General Population and Prisoners

As seen below in Table 1, Kentucky state and federal prisoners represent 0.5% and 0.7% of Kentucky's general population and adult population, respectively. Unlike the general population in which the proportion of males and females is basically equal, Kentucky's prison population is predominantly male (88.1%). Although white race is most common among both prisoners and the general population in Kentucky, there is a larger proportion of African American/black prisoners (22.2%) than in the general population (7.8%). In contrast, after whites in Kentucky's general population, the most common races are those identified by two or more, followed by other, Asians, and then African Americans/blacks. By observation, with the exception of African Americans/blacks, there appear to be less other minorities in prison in Kentucky versus in the state's general population.

Table 1: Demographics of the General Population and Prisoners in Kentucky

Demographic Characteristic	General Population <i>Count No. (%)</i>	Prisoners <i>Count No. (%)</i>
<i>Total</i>	4,339,367	21,701 (0.5)
<i>Age 18 years and over</i>	3,315,996 (76.4)	21,701 (0.7)
<i>Sex</i>	<i>Count No. (% total population)</i>	<i>Count No. (% prisoners)</i>
Male	2,134,952 (49.2)	19,114 (88.1)
Female	2,204,415 (50.8)	2,587 (11.9)
<i>Ethnicity</i>	<i>Count No. (% total population)</i>	<i>Count No. (% prisoners)</i>
White	3,809,537 (87.8)	16,350 (75.3)
African American/Black	337,520 (7.8)	4,807 (22.2)
Hispanic	-	278 (1.3)
Asian	48,930 (11.3)	31 (0.14)
American Indian and Alaska Native	10,120 (2.3)	17 (0.08)
Native Hawaiian and Pacific Islander	2,501 (0.05)	0
Other	55,551 (12.8)	-
Identified by two or more	75,208 (17.3)	198 (0.91)
Not known	-	16 (0.07)
Did not report	-	4 (0.01)

Data sources: counts from 2010 U.S. Census Bureau⁶² data and 2015 Bureau of Justice Statistics (BJS), National Prisoner Statistics Program⁴⁰ (Kentucky state and federal prisoners); percentages were calculated.

The Prevalence and Burden of Hepatitis C Virus in Kentucky

Estimates of the number of infected prisoners in Kentucky calculated via reference HCV prevalence estimates included the following: estimates of 3,775 to 7,334 with the lowest and

Table 2: Estimates of HCV Prevalence and the Burden of Hepatitis C Among Kentucky Noninstitutionalized Adults and Prisoners, and Prison Admissions and Releases

Population	Total No.	HCV Prevalence (%)		No. of Infected Persons	
		Estimate	95% CI	Estimate	95% CI
Noninstitutionalized 18 years and over	3,315,996	1.63	1.42-1.92	54,200	47,200-63,800
Kentucky Prisoners					
Incarcerated in North America	21,701	29	24-34	6,293	5,208-7,378
Incarcerated in U.S.		23.1	7.5-44.0	5,010	1,630-9,550
State Prisoners in U.S.		17.4	-	3,775	-
State Prisoners in Kentucky		33.8	18.3-49.3	7,334	3,971-10,698
Calculated Mean Estimates		25.8	14.5-37.1	5,598	3,146-8,051
Kentucky Prison Admissions					
Incarcerated in North America	19,356	29	24-34	5,613	4,645-6,581
Incarcerated in U.S.		23.1	7.5-44.0	4,470	1,450-8,520
State Prisoners in U.S.		17.4	-	3,367	-
State Prisoners in Kentucky		33.8	18.3-49.3	6,542	3,542-9,542
Calculated Mean Estimates		25.8	14.5-37.1	4,993	2,806-7,181
Kentucky Prison Releases					
Incarcerated in North America	18,476	29	24-34	5,436	4,499-6,373
Incarcerated in U.S.		23.1	7.5-44.0	4,270	1,390-8,130
State Prisoners in U.S.		17.4	-	3,261	-
State Prisoners in Kentucky		33.8	18.3-49.3	6,244	3,381-9,108
Calculated Mean Estimates		25.8	14.5-37.1	4,776	2,679-6,854

Data sources and analysis: The left column presents the populations of research interest (Kentucky state and federal prisoners, admissions, and releases), HCV prevalence reference estimates' population sources, and the primary outcome of the analysis in this table, calculated mean estimates with 95% CIs of anti-HCV prevalence and number of infected persons among the Kentucky research populations. The next column lists populations' count totals from 2010 U.S. Census Bureau⁶² data (noninstitutionalized population) and 2015 Bureau of Justice Statistics (BJS), National Prisoner Statistics Program⁴⁰ (Kentucky state and federal prisoners, admissions, and releases). HCV prevalence and number of infected persons among those noninstitutionalized 18 years and over in Kentucky in 2010 are from Rosenberg et al.³⁶ Reference incarcerated populations' HCV prevalence estimates with 95% CIs were used from the following sources: North America's incarcerated population (U.S. and Canada) from Larney et al.⁴²; U.S. incarcerated populations (state prisons and local jails) weighted mean prevalence from Edlin et al.³⁴; 2006 U.S. median HCV seroprevalence among state prisoners from Varan et al.⁴³; and Kentucky state prisoners' calculated sample mean of confirmed HCV prevalence, not true population prevalence, from Humbaugh⁶³ and Kentucky Department of Corrections' (KDOC) 2010-2013 data (see Table 3). Estimates with 95% CIs of number of infected people among the Kentucky research populations, calculated from their total numbers and the reference HCV prevalence estimates, are presented in the last two columns.

highest 95% CI bounds of 1,630 and 10,698 among Kentucky state and federal prisoners; estimates of 3,367 to 6,542 with the lowest and highest 95% CI bounds of 1,450 and 9,542 among Kentucky prison admissions; and estimates of 3,261 to 6,244 with the lowest and highest 95% CI bounds of 1,390 and 9,108 among Kentucky prison releases.

The reference HCV prevalence estimates' overall calculated mean and 95% CI of 25.8% (14.5%-37.1%) served as the approximation of HCV prevalence among Kentucky prisoners, admissions, and releases, and was used to calculate the following estimates of the number of infected persons in each of those respective populations: 5,598 (3,146-8,051 95% CI) infected Kentucky state and federal prisoners; 4,993 (2,806-7,181 95% CI) infected Kentucky prison admissions; and 4,776 (2,679-6,854 95% CI) infected Kentucky prison releases.

The calculated mean HCV prevalence estimate of 25.8% among Kentucky prisoners is nearly 16 times that of the Kentucky non-institutionalized adults reference estimate. Also, comparing the calculated mean number of HCV infected Kentucky prisoners to available data about actual diagnosed prisoners from Humbaugh⁶³ (n=1030) and Beckman³³ (n=1,631) suggests there could be around 3,967-4,568 undiagnosed HCV infected prisoners in Kentucky.

Hepatitis C Screening and Treatment in Kentucky State Prisons, 2010 to 2013

In Kentucky state prisons from 2010 to 2013, the number of inmates screened for HCV steadily increased from 835 in 2010 to 905 in 2011, then jumping to its peak of 1,248 in 2012, after which it noticeably dropped to 736, as seen below in Table 3 and Figure 2. Of 3,724 inmates screened for HCV during that 4-year period, nearly one third (n=1,205, 32.4%) were confirmed HCV positive, but only 175 (14.5%) started treatment, leaving 1,030 (85.5%) untreated.⁶³ The 2013 decrease in HCV screening was actually associated with the highest number (n=343) and proportion (46.6%) of confirmed cases of HCV as well as the highest

Table 3: HCV Screening and Initiation of Treatment Among Kentucky Inmates, 2010 to 2013

	<i>Inmates in Kentucky State Prisons</i>						
<i>Year</i>	Screened for HCV	Confirmed HCV Positive		Started HCV Treatment		Untreated HCV Positive	
	<i>Count No.</i>	<i>Count No.</i>	<i>%</i>	<i>Count No.</i>	<i>%</i>	<i>Count No.</i>	<i>(%)</i>
2010	835	300	35.9	47	15.7	253	84.3
2011	905	256	28.3	50	19.5	206	80.5
2012	1,248	306	24.5	35	11.4	271	88.6
2013*	736*	343*	46.6	43*	12.5	300	87.5
Total**	3,724**	1,205**	32.4	175**	14.5	1,030	85.5
Mean	931	301	33.8	44	14.8	258	85.2
Median	870	303	32.1	45	14.1	262	85.9

Data sources and analysis: Humbaugh's presentation⁶³ provided KDOC counts of the number of Kentucky state prison inmates each year from 2010-2013, who received HCV screening, positive confirmatory testing, and treatment initiation. Data analysis included the above calculated proportions (%) as well as calculation of both the number and proportions (%) of untreated HCV positive Kentucky prisoners along with the overall means and medians of each category.

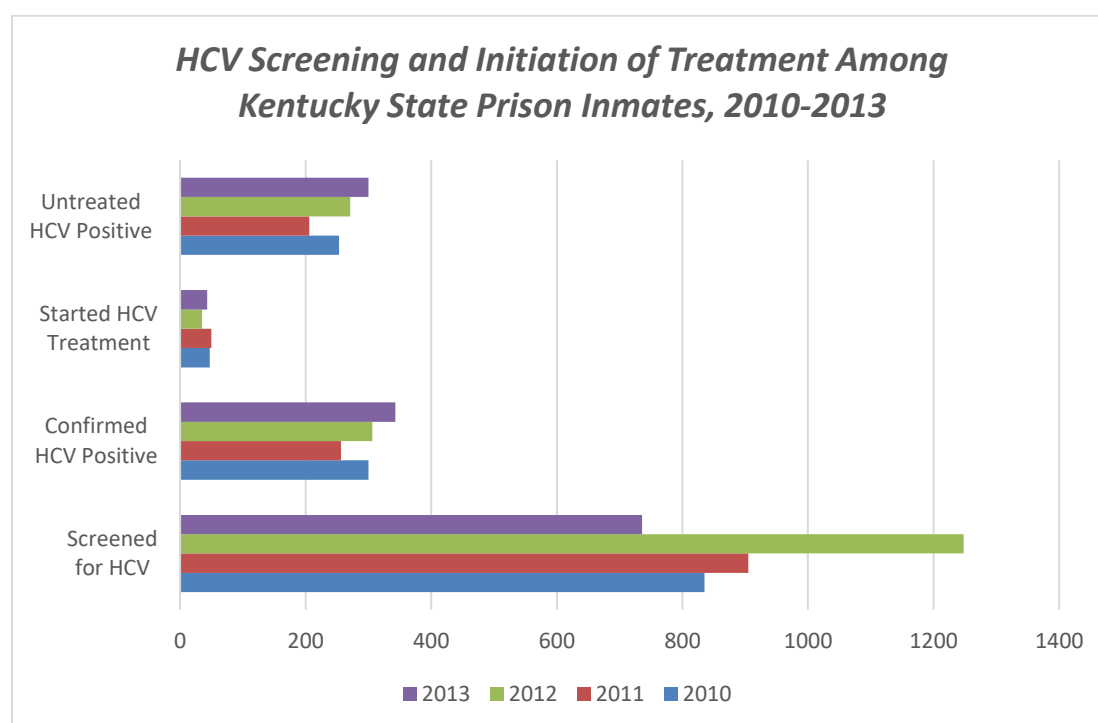


Figure 2 – Data sources and analysis: Humbaugh's presentation⁶³ provided KDOC counts of the number of Kentucky state prison inmates each year from 2010-2013, who received HCV screening, positive confirmatory testing, and treatment initiation; the number untreated HCV positive Kentucky prisoners, proportions (%) and overall means and medians were calculated for each category (see Table 3). This is a graphical representation of those HCV management practices (y-axis) and the respective number of inmates impacted (x-axis) per year from 2010-2013.

number of untreated HCV infected inmates (n=300) out of all 4 years.⁶³ In contrast, more inmates were screened in 2012 than any of the other years, and 2012 had the second highest number (n=306) but the lowest proportion (24.5%) of confirmed HCV cases and the highest proportion (88.6%) of HCV positive inmates left untreated.⁶³

Although treatment numbers were low throughout the period with only 35-50 (11.4%-19.5%) infected prisoners starting treatment each year, treatment initiation markedly fell from 19.5% (n=50) in 2011 to 11.4% (n=35) in 2012 and remained low at 12.5% (n=43) in 2013.⁶³ As a result, the vast majority of hepatitis C infected inmates in Kentucky state prisons did not receive treatment, and between 206-300 HCV infected inmates or 80.5%-88.6% remained untreated each year from 2010 to 2013 (see Table 3 above).⁶³ Using the most recent Kentucky Medicaid estimate for average cost of \$83,735 to treat one HCV patient, the approximate current cost to treat HCV in the 1,030 untreated prisoners would be \$86,247,050.⁵⁶

Costs of Hepatitis C Screening and Treatment in Kentucky Prison Populations

Presented in Table 4 below, estimated total costs for screening range from about \$2.20 million (\$1.41-\$2.99 million 95% CI) for Kentucky prison releases, to \$2.30 million (\$1.47-\$3.14 million 95% CI) for Kentucky prison admissions, and up to \$2.58 million (\$1.65-\$3.52 million 95% CI) for Kentucky state and federal prisoners. If there were currently around 21,701 Kentucky state and federal prisoners and 19,356 prison admissions in Kentucky in 2017, one-time screening of both current prisoners and 2017 admissions could cost about \$4.89 million (\$3.12-\$6.65 million 95% CI).⁴⁰

Use of the recent average per patient Kentucky Medicaid HCV treatment cost of \$83,735 led to the following treatment cost estimates: \$469 million (\$263-\$674 million 95% CI) for prisoners, \$418 million (\$235-\$601 million 95% CI) for admissions, and \$400 million (\$224-

Table 4: Estimated Costs of Screening and Treatment Among Kentucky State and Federal Prisoners, Admissions, and Releases

Costs of Initial HCV Screening			
Kentucky Federal & State...		Costs for Anti-HCV testing	
Prisoners	21,701	\$455,721	
Admissions	19,356	\$406,476	
Releases	18,476	\$387,996	
Costs of HCV Confirmatory and Follow-up Testing, Total Screening, and Treatment Scenarios			
Kentucky Prisoners			
No. of Infected Prisoners	5,598	3,146	8,051
Costs	Estimate	95% CI	
Confirmatory Testing	\$151,146	\$84,942	\$217,377
HCV Genotype Tesing	\$1,976,094	\$1,110,538	\$2,842,003
Total Costs for Screening	\$2,582,961	\$1,651,201	\$3,515,101
Treatment Costs (MA)	\$468,748,530	\$263,430,310	\$674,150,485
Treatment (25% discount to MA)	\$351,561,398	\$197,572,733	\$505,612,864
Treatment (50% discount to MA)	\$234,374,265	\$131,715,155	\$337,075,243
Kentucky Prison Admissions			
No. of Infected Admissions	4,993	2,806	7,181
Costs	Estimate	95% CI	
Confirmatory Testing	\$134,811	\$75,762	\$193,887
HCV Genotype Tesing	\$1,762,529	\$990,518	\$2,534,893
Total Costs for Screening	\$2,303,816	\$1,472,756	\$3,135,256
Treatment Costs (MA)	\$418,088,855	\$234,960,410	\$601,301,035
Treatment (25% discount to MA)	\$313,566,641	\$176,220,308	\$450,975,776
Treatment (50% discount to MA)	\$209,044,428	\$117,480,205	\$300,650,518
Kentucky Prison Releases			
No. of Infected Releases	4,776	2,679	6,854
Costs	Estimate	95% CI	
Confirmatory Testing	\$128,952	\$72,333	\$185,058
HCV Genotype Tesing	\$1,685,928	\$945,687	\$2,419,462
Total Costs for Screening	\$2,202,876	\$1,406,016	\$2,992,516
Treatment Costs (MA)	\$399,918,360	\$224,326,065	\$573,919,690
Treatment (25% discount to MA)	\$299,938,770	\$168,244,549	\$430,439,768
Treatment (50% discount to MA)	\$199,959,180	\$112,163,033	\$286,959,845

Data sources, references, cost estimate sources, and analysis: Total Kentucky state and federal prisoners, admissions, and releases (top left) were also used in Table 2 from 2015 Bureau of Justice Statistics (BJS), National Prisoner Statistics Program.⁴⁰ The calculated estimates and 95% CIs of number of infected prisoners, admissions, and releases are from Table 2, and were used to calculate costs estimates for confirmatory testing, genotype testing, and treatment. Individual screening costs to calculate the above estimates were from the 2017 *Kentucky Medicaid Clinical Diagnostic Laboratory Fee Schedule*,⁶⁸ including the following: Initial screening via “Hep c ab test confirm” \$21; confirmatory testing via “Hepatitis c rna dir probe” \$27; “Genotype dna/rna hep c” \$353. Treatment costs were based on the most recent Kentucky Medicaid (MA) estimate for average cost of \$83,735 to treat one HCV patient as well as 25% and 50% discounts applied for costs of \$62,801 and \$41,868, respectively.⁵⁶

\$574 million 95% CI) for releases.⁵⁶ Applying a 25% discount, results in a per patient HCV treatment cost estimate of \$62,801 and estimated costs for prisoners at \$352 million (\$198-\$506 million 95% CI), for prison admissions at \$314 million (\$176-\$451 million 95% CI), and for prison releases at \$300 million (\$168-\$430 million 95% CI). A 50% discount would lower per person HCV treatment cost to about \$41,868, yielding cost estimates as follows: \$234 million (\$132-\$337 million 95% CI) for prisoners, \$209 million (\$117-\$301 million 95% CI) for admissions, and \$200 million (\$112-\$287 million 95% CI) for releases. So, if one-time screening of current prisoners and admissions was performed, estimated costs to treat HCV cases detected could range from \$887 million (\$498 million – \$1.28 billion 95% CI) for full price down to \$443 million (\$249-\$638 million 95% CI) with a 50% discount.

Comparing these screening and treatment cost estimates to the Kentucky enacted FY2017 budget, specifically considering the \$57,086,000 KDOC medical services budget (Figure 3) and the \$10,578,419,600 Kentucky Medicaid Services benefits budget (Figure 4), allows assessment of financial feasibility.⁶⁴

Since KDOC medical services budget only applies to Kentucky state prisoners not federal prisoners, which represent roughly 55% of the combined total, applicable cost estimates and budget proportions (%) were calculated and are presented below in Figure 3. Screening all Kentucky state prisoners was estimated to cost \$1.42 million (\$908 thousand-\$1.93 million 95% CI), which would require approximately 2.49% (1.59%-3.39% 95% CI) of the KDOC medical services budget. On the other hand, treatment estimates for Kentucky state prisoners alone and their corresponding percentages of the KDOC medical services budget range from about \$129-\$258 million (226%-452%) with 95% CIs ranging from a 50% discount lower bound of \$72.4 million (127%) to the full price Kentucky Medicaid upper bound of \$371 million (650%).

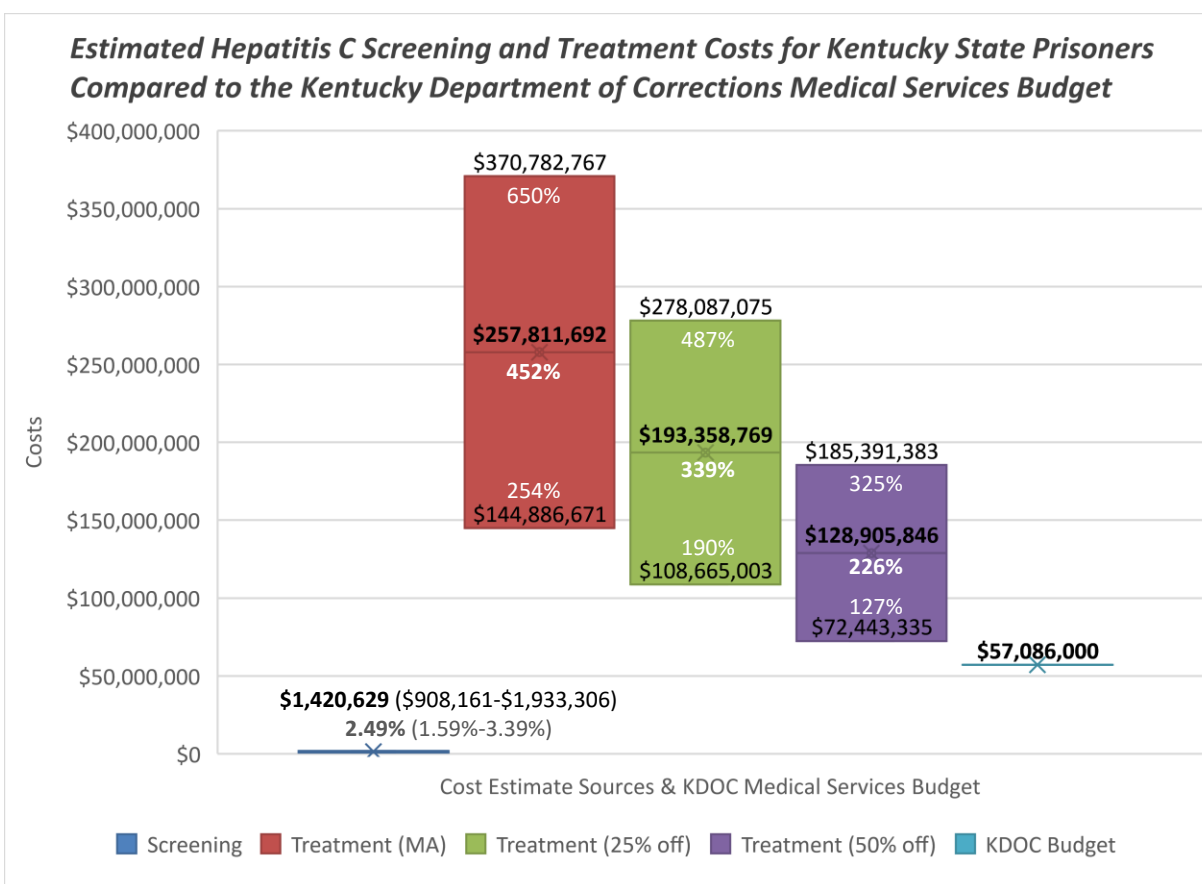


Figure 3 – Data sources and analysis: Since 11,987 Kentucky state prisoners⁶⁵ made up 55% of the total 21,701 Kentucky state and federal prisoners⁴⁰ on December 31, 2015, assuming HCV cases are proportionately distributed between state and federal prisoners, Kentucky state prisoner HCV screening and treatment cost estimates and 95% CIs (listed in black) were calculated as 55% of total Kentucky prisoners' cost estimates from Table 4 along with corresponding proportions (% listed in white) and 95% CIs of the \$57,086,000 KDOC medical services budget they would consume.⁶⁴ Treatment costs were based on the most recent Kentucky Medicaid (MA) estimate for average cost of \$83,735 to treat one HCV patient as well as 25% and 50% discounts (% off) applied for costs of \$62,801 and \$41,868, respectively.⁵⁶

If the entire KDOC medical services budget was used solely to purchase HCV treatment regimens based on per patient HCV treatment cost estimates, it could cover the following mutually exclusive options: 681 treatment regimens at the \$83,735 Kentucky Medicaid cost; 909 treatment regimens at the \$62,801 25% discounted cost; or 1,363 treatment regimens at the \$41,868 50% discounted cost. Thus, even when only considering costs of HCV screening and treatment for Kentucky state prisoners, the KDOC medical services budget coverage is limited.

In contrast, the \$10.6 billion Kentucky Medicaid Services benefits budget is about 185

times the \$57.1 million KDOC medical services budget.⁶⁴ So, none of the screening or treatment estimates for Kentucky federal and state prisoner releases, even combined, exceed the Kentucky Medicaid Services benefits budget (see Figure 4 below). The estimated cost to screen the total Kentucky prisoner releasee population for HCV is only 0.02% (0.01%-0.02% 95% CI) of the Kentucky Medicaid Services benefits budget, and similar treatment cost estimate percentages range from 1.89%-3.78% with 95% CIs ranging from 1.06% to 5.43% for the 50% discount lower bound to the current Kentucky Medicaid cost estimate's upper bound, respectively. In other words, all Kentucky state and federal prison releasees' HCV screening and treatment individual cost estimates are less than 5.5% of the Kentucky Medicaid Services benefits budget.

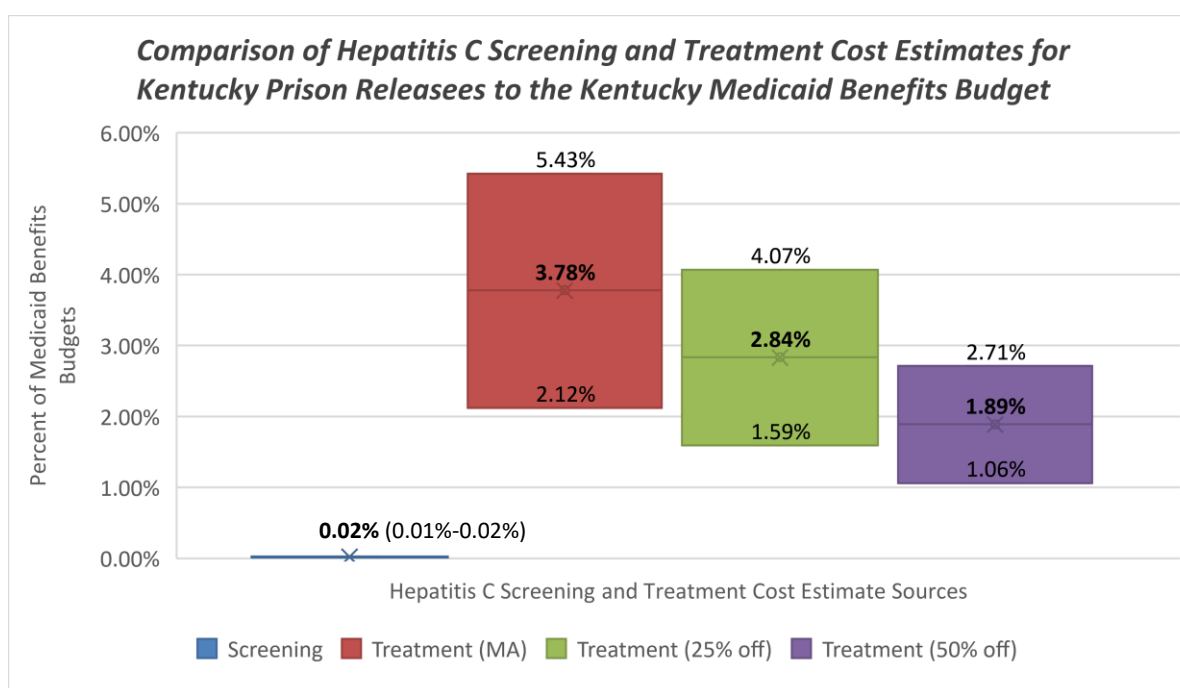


Figure 4 – Data sources and analysis: HCV screening and treatment cost estimates for Kentucky prison releasees from Table 4 were used to estimate percentages and 95% CIs of the \$10,578,419,600 Kentucky Medicaid (MA) Services benefits budget they would require.⁶⁴

Consideration of Costs of Failing to Treat Prisoners Prior to Release

First of all, the results of the example scenario of HCV transmission from the untreated infected prisoners to 1,030 community members upon release are reported here. The “Natural

History of Infection” section of Table 5 contains the estimated number of affected cases for each stage in the course of untreated HCV infections. The assumed spontaneous clearance of acute HCV in 15%-25%, an estimated 154-257 of the new HCV cases, within 6 months as well as the progression to chronic HCV (CHC) infection in 55%-85% or 566-875 of the new cases are both relevant for estimations of potential costs secondary to HCV Transmission and the new cases in this analysis, as further described below and in Table 5.

Table 5: Estimated Costs Secondary to HCV Transmission from Untreated Prisoners

EXAMPLE SCENARIO: HCV Transmission in the Community Upon Infected Prisoner Release <i>If each untreated infected prisoner infects at least 1 other person in the community upon release → 1,030 new cases of undiagnosed acute HCV infection</i>		
Natural history of HCV infection	Proportion (%) of cases affected	Estimated number of affected cases
<i>Symptomatic acute HCV infection</i>	20-30%	113-262
<i>Spontaneous clearance of acute HCV</i>	15-25% within 6 months	154-257
<i>Chronic HCV (CHC) infection</i>	55-85%	566-875
<i>Cirrhosis</i>	20-30% of CHC patients over ~25-30 years	113-262
<i>Clinical Decompensation</i>	2-5% of persons with cirrhosis per year	2-13 per year
<i>Hepatocellular Carcinoma</i>	1-4% of persons with cirrhosis per year	1-10 per year
EXAMPLE SCENARIO: Potential Costs Secondary to HCV Transmission and the New Cases		
Estimated Costs for:	Per HCV infected person	TOTAL
Screening of all cases (n=1030)	\$2,873	\$2,959,190
HCV treatment for all cases (n=1030)	\$83,735	\$86,247,050
HCV treatment for CHC (n=566-875)	\$83,735	\$47,394,010 - 73,268,125
Total Screening and Treatment Costs up to \$89,206,240		

References and cost estimate sources: Most recent Kentucky Medicaid estimate for average cost to treat one HCV patient: \$83,735.⁵⁶ Reference proportions (%) were used to determine natural history of HCV case estimates here.^{4,5,21} One-time screening outside prisons \$2,873.^{17,66}

Assuming all 1,030 new community HCV cases were screened at a cost of \$2,873, their total screening costs were found to be nearly \$3 million.^{17,66} If all of these new cases were successfully diagnosed and treated, their estimated total treatment costs would equal about \$86.2 million, plus the \$3 million for screening would yield a total cost of about \$89.2 million. For the

566-875 CHC cases in the community, estimated costs for HCV treatment were \$47.4 to \$73.3 million.

Last, potential healthcare costs of failing to treat HCV in these populations of interest were estimated using a reference estimate of about \$100,000 average lifetime healthcare cost for hepatitis C per patient, excluding the additional estimated \$280,000 yearly costs for each liver transplant patient.⁶⁷ Assuming the 1,030 HCV infected Kentucky state prisoners from 2010-2013 all have CHC and never receive treatment, their collective average lifetime healthcare costs for HCV could be around \$103 million without liver transplantation. If each of those hepatitis C infected prisoners infect at least one person in the community upon release, as demonstrated in the example scenario, of the 1,030 new cases between 566-875 would develop CHC, which could cost another \$56.6-\$87.5 in HCV related lifetime healthcare costs if left untreated. So, failing to treat both the 1,030 prisoners and the 566-875 new community cases of CHC could cost about \$160-\$191 million in hepatitis C lifetime healthcare costs alone. Suppose none of the estimated 5,598 (3,146-8,051 95% CI) HCV infected Kentucky state and federal prisoners ever received treatment for hepatitis C, their associated lifetime healthcare costs could be estimated at \$560 million (\$315-\$805 million 95% CI). In summary, failure to treat hepatitis C is also a costly option, especially if doing so contributes to HCV transmission and new cases of infection.

DISCUSSION & RECOMMENDATIONS

Since HCV infected prisoners released back into society, especially those with history of IDU, are presumably among the populations at greatest risk to further perpetuate and exacerbate the triad of epidemics—incarceration, opioid overdose deaths secondary to substance use disorders (SUDs), and hepatitis C—currently overwhelming Kentucky and the U.S., they must be considered as potential multidisciplinary intervention targets. The purpose of this research

was to examine Kentucky corrections' HCV screening and treatment policy and practice applicable to prisoners and to explore the roles they may play in combatting the hepatitis C epidemic, in particular. Further discussion and interpretation of research results include:

Following Evidence-based Hepatitis C Guidelines in Kentucky Prisons Is Recommended
White Males Have Been Particularly Impacted
Hepatitis C Surveillance Among Kentucky Prisoners Is Inadequate
High Cost Hepatitis C Treatment Incentivizes Avoidance of Screening
Burden of Hepatitis C Treatment Costs Is Unbearable for Kentucky Corrections' Budget
Failure to Treat Hepatitis C May Further Enable Its Costly Spread in the Community

Limitations of this research will be briefly reviewed with their respective research topics.

Then, knowledge acquired from this research is used to make policy and practice recommendations about HCV screening and treatment of prisoners in Kentucky. The high cost of the effective and curative DAA hepatitis C treatment regimens is the greatest obstacle hindering HCV screening, diagnosis, and treatment among prisoners and the general population in Kentucky and the U.S. Historically, the HIV/AIDS epidemic posed similar challenges to this nation that have been addressed with noteworthy success via AIDS Drug Assistance Programs (ADAPs) and the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, now called the Ryan White Program, which played a vital role in reducing treatment costs and improving health outcomes.^{19,32,44,69,70} Advocacy to establish an analogous program for HCV treatment has been increasing.^{19,32,44,69,70} According to Trooskin and colleagues,⁶⁹ "An ADAP analogue for HCV treatment would accomplish similar goals by facilitating focused price negotiations, achieving transparency, [...] increasing access, [...] contain[ing] costs." Therefore, establishment of such a program in response to the U.S. HCV epidemic is recommended as a crucial component of its solution. However, since hepatitis C is one of three costly, complex, interconnected epidemics devastating the people and financial resources of Kentucky, time cannot be wasted while waiting for change to occur at the federal level. Consequently, state

level strategies to address cost and other barriers are explored below, keeping in mind that no single recommendation or strategy will solve the hepatitis C epidemic; instead, multifaceted, multidisciplinary, collaborative and integrative solutions may be the only way to eradicate HCV in the Commonwealth of Kentucky and the U.S.

Following Evidence-based Hepatitis C Guidelines in Kentucky Prisons Is Recommended

Unlike the detailed BOP HCV guidelines, hepatitis C management among prisoners is only vaguely alluded to in the publicly available *13.2 Health Maintenance Services* and *13.10 Serious Infectious Disease* from the KDOC *Medical and Health Care Services Policies and Procedures*.^{†60,61} Review of these nonspecific policies and procedures alone provides little information about the KDOC's actual HCV screening and treatment practices. However, the disclaimer on the KDOC source webpage, provided in the footnote below, implies there could be a "secured," more specific HCV policy and procedure, unavailable to the public. So, lack of contact with an official KDOC representative, as a source of clarification and additional information about the department's approach to HCV in Kentucky state prisoners, is a major limitation of this research. Future research should include collaboration with the KDOC to fill information gaps, such as whether or not a secured HCV policy and procedure exists, and to work together to determine achievable solutions. Regardless of the specific details of current KDOC HCV management policy and practice, striving to implement the BOP, AASLD and IDSA guidelines should be both recommended and encouraged.

[†] "The Policies and Procedures provided at this Web site are unofficial versions and are intended for informational purposes only. They are provided by the Department as a service to the public. They are subject to change at any time and do not include the secured Policies and Procedures of the Department. The Department does not guarantee the accuracy or completeness of the postings."^{61,62}

White Males Have Been Particularly Impacted

Regarding demographics, white males make-up the vast majority of Kentucky's prison population and have been particularly impacted by this triad of epidemics, which further supports the importance of targeting that population with multidisciplinary evidence-based interventions.⁶ Limitations of this demographic comparison, some of which may be addressed in future research include: the general population data from the 2010 U.S. Census Bureau⁶² is relatively outdated compared to 2015 Kentucky state and federal prisoners data from the Bureau of Justice Statistics (BJS), National Prisoner Statistics Program⁴⁰; failure to further stratify populations by age; lack of demographic information with respect to hepatitis C in Kentucky's general and prison populations.

Hepatitis C Surveillance Among Kentucky Prisoners Is Inadequate

This attempt to estimate HCV prevalence and the burden of hepatitis C among Kentucky prisoners in the absence of high quality Kentucky specific seroprevalence data underscores the need for improved hepatitis C surveillance in this population at the intersection of this triad of epidemics. The estimated overall mean (95% CI) HCV prevalence among Kentucky prisoners as 25.8% (14.5%-37.1%) is nearly 16 times that of the Kentucky non-institutionalized adults reference estimate, and it was used to estimate the number of infected persons as follows: 5,598 (3,146-8,051 95% CI) infected Kentucky state and federal prisoners; 4,993 (2,806-7,181 95% CI) infected Kentucky prison admissions; and 4,776 (2,679-6,854 95% CI) infected Kentucky prison releases. Last, possible undiagnosed HCV infected prisoners in Kentucky were estimated to range from 3,967-4,568. Both known HCV infected prisoners left untreated and those undiagnosed may further fuel this epidemic by spreading HCV to currently uninfected members of the community and increasing hepatitis C incidence. The relative lack of Kentucky specific

surveillance data significantly limits the accuracy of research estimates of the HCV prevalence and burden in Kentucky, which may be underestimated or overestimated secondary to misclassification.

High Cost Hepatitis C Treatment Incentivizes Avoidance of Screening

Review of Kentucky state prisons' HCV screening and treatment 2010 to 2013 KDOC data provides some insight about HCV management practices among Kentucky prisoners.⁶³ During that time period, essentially one third (n=1,205, 32.4%) of the 3,724 inmates screened were confirmed HCV positive, but only 175 (14.5%) started treatment, leaving 1,030 (85.5%) untreated. HCV screening had been rising until peaking in 2012 at 1,248 and then falling to 736 in 2013. Not only were treatment numbers low with 35-50 (11.4%-19.5%) infected prisoners starting treatment each year, but treatment initiation also markedly fell from 19.5% (n=50) in 2011 to 11.4% (n=35) in 2012 and remained low at 12.5% (n=43) in 2013.

With the high cost of DAAs as a known barrier to HCV screening and treatment, especially in correctional settings, the decline in both coinciding with DAAs' arrival to the market is probably not simply coincidence but more likely supporting evidence to that effect.^{32,33} In other words, the current price of HCV medications incentivizes avoidance of HCV screening and diagnosis to indirectly avoid hepatitis C treatment costs in budget limited settings such as prisons. The combination of high cost HCV treatment regimens and inadequate budget funding, to cover treatment cost increases from diagnosing more new cases of HCV via screening, essentially forces corrections officials to limit screening, which may perpetuate the presence of a pool of undiagnosed HCV carriers in high-risk correctional populations. The current cost to treat HCV in the 1,030 untreated prisoners from 2010-2013 would be an estimated \$86,247,050, which is 151% of the current KDOC medical services budget.⁵⁶ The significant expense of HCV

treatment also contributes to treatment access limitations among known hepatitis C infected patients, especially in corrections, despite prisoners' Constitutional right to healthcare.³³

Burden of Hepatitis C Treatment Costs Is Unbearable for Kentucky Corrections' Budget

Estimation of HCV screening and treatment costs among Kentucky state and federal prisoners, admissions, and releases, and their comparison to applicable budgets helps assess feasibility and determine future directions. Screening cost estimates ranged from about \$2.20 million (\$1.41-\$2.99 million 95% CI) for Kentucky prison releases to up to \$4.89 million (\$3.12-\$6.65 million 95% CI) for one-time screening of both current Kentucky state and federal prisoners and 2017 admissions. Based on the full \$83,735 Kentucky Medicaid average HCV treatment cost per patient, cost estimates ranged from as low as the 50% discounted estimate of \$200 million (\$112-\$287 million 95% CI) for Kentucky prison releases to as high as \$887 million (\$498 million – \$1.28 billion 95% CI) to treat all HCV cases diagnosed via one-time screening of both current Kentucky state and federal prisoners and 2017 admissions.⁵⁶

Furthermore, comparing calculated HCV screening and treatment cost estimates for Kentucky state prisoners to the \$57,086,000 KDOC 2017 medical services budget makes the obscene costs of hepatitis C treatment appear to be an insurmountable obstacle to addressing the hepatitis C epidemic in Kentucky correctional populations.⁶⁴ HCV treatment cost estimates and their corresponding percentages of the KDOC medical services budget ranged from about \$129-\$258 million (226%-452%) with 95% CIs from a 50% discount lower bound of \$72.4 million (127%) to the full price Kentucky Medicaid upper bound of \$371 million (650%). If the entire KDOC medical services budget was used only for hepatitis C treatment regimens with a 50% discount it would still only cover treatment for 1,363 prisoners, which would not have been enough to treat all 1,631 cases known as of January 1, 2015, only 2 (0.12%) of which were being

treated at that time.³³ Screening Kentucky state prisoners was estimated to cost \$1.42 million (\$908 thousand-\$1.93 million 95% CI) and would require approximately 2.49% (1.59%-3.39% 95% CI) of the KDOC medical services budget.

On the other hand, the \$10.6 billion Kentucky Medicaid Services benefits budget is about 185 times the \$57.1 million KDOC medical services budget.⁶⁴ So, estimated HCV cost percentages of the Kentucky Medicaid Services benefits budget for the total Kentucky prisoner releasee population were only 0.02% (0.01%-0.02% 95% CI) for screening and from 1.89%-3.78% with 95% CIs ranging from the 50% discount lower bound of 1.06% to the current Kentucky Medicaid cost estimate's upper bound 5.43% for treatment, respectively. Yet, despite the blatant difference in available KDOC medical services and Kentucky Medicaid Services budgetary funds, both are restricting access to HCV treatment in the midst of the intensifying hepatitis C epidemic, which is evidence of the need for creative funding approaches to overcome financial barriers such as expensive treatment.^{32,33}

Failure to Treat Hepatitis C May Further Enable Its Costly Spread in the Community

Although rather simplistic, the scenario of HCV infection transmission from the untreated prisoners to community members (n=1,030) upon release allows consideration of various potentially preventable costs and consequences. For example, based on the natural history of HCV infection, the 1,030 new cases of HCV in the community will include the following: 113-262 cases if symptomatic acute HCV infection; 154-257 cases of acute HCV infection that spontaneous clear within 6 months versus 566-875 that become CHC; 113-262 cases of CHC progressing to cirrhosis over 25-30 years, of which 2-13 per year will clinically decompensate and 1-10 per year will develop HCC.^{4,5,21} Theoretically, these cases and their complications

could be prevented by treating prisoners HCV prior to their release to prevent HCV transmission to uninfected individuals in the general population.¹⁷

Costs for HCV screening and treatment of the new cases in the community could be up to \$89.2 million. If left untreated, the lifetime healthcare costs for hepatitis C in the 1,030 prisoners and the 566-875 new community cases of CHC could add up to around \$160-\$191 million, excluding liver transplantation. Similarly, failure to treat an estimated 5,598 (3,146-8,051 95% CI) HCV infected Kentucky state and federal prisoners could ultimately result in \$560 million (\$315-\$805 million 95% CI) lifetime HCV associated healthcare costs. Despite their limitations, these lifetime hepatitis C healthcare cost estimates allow initial consideration of the magnitude of costs that might be avoided by screening, diagnosing, and treating HCV to prevent transmission. An important limitation of these estimates is their failure to accurately account for the time value of money, rendering them incomparable to present cost estimates. This rudimentary analysis is also limited by the absence of other direct, indirect, monetary, and nonmonetary costs and more complex financial and economic modeling, including cost-effectiveness, which are all essential considerations for future research.

Recommendations and Strategies to Overcome Barriers in Kentucky

With prisoners at the center of the triad of epidemics burdening the Commonwealth of Kentucky, instead of asking whether or not prisoners should be targeted with relevant interventions, the question should be how can Kentucky target prisoners to combat these tangled threats, including hepatitis C. Since these are population health problems, they demand evidence-based population level solutions, among which policy is a powerful lever for change and effective collaboration and integration are essential.⁷¹⁻⁷³ So, as leaders develop plans to address these epidemics, they should seek the knowledge, wisdom, and insight of evidence-based

resources, such as those of Prybil, Scutchfield, Hanleybrown, and their colleagues, for guidance about how to implement successful collaborative population health initiatives.⁷¹⁻⁷³

The high cost of hepatitis C treatment in the context of budgetary constraints has been significantly limiting HCV screening and treatment among prisoners and Medicaid beneficiaries in Kentucky and throughout the U.S.^{32,33} With KDOC medical services budget around \$57 million versus the Kentucky Medicaid Services benefits budget at approximately \$10.6 billion, this research cost analysis highlights how quickly KDOC funds would be exhausted in efforts to treat HCV before even being able to treat all known cases and at the expense of all other medical services.⁶⁴ Comparison of these budgets also illuminates the substantial funding disparity. Although prisoners have a constitutional right to healthcare and are the center of this costly triad of epidemics, state corrections' budgets are not funded to pay for the high burden of healthcare needs among their medically and socially complex incarcerated populations.

Enhanced collaboration and integrated funding streams may be imperative for resource limited states, like Kentucky, to be able to target prisoners with multi-disciplinary interventions to curb these epidemics without bankrupting departments within state governments. A few other states' DOC have had success using the 340B drug discount program to obtain the lowest prices for DAAs among state DOC, which may be an important approach for KDOC to consider in partnership with the University of Kentucky (UK) and federally qualified health centers (FQHS).³³ Another possible strategy for Kentucky that at least 18 states have utilized is screening prisoners upon release and enrolling them in Medicaid at that time, to improve HCV diagnosis and surveillance and connect prisoners with healthcare resources before they enter the community.³³ Concerted efforts to actively seek relevant grant funding opportunities cannot be overemphasized. Since Kentucky has been so profoundly impacted by this triad of epidemics,

one or more demonstration projects could provide opportunities to explore creative funding solutions and multi-disciplinary interventions targeting prisoners, to implement and evaluate enhanced prisoner HCV surveillance and treatment options, and to ultimately inform policy and practice to prevent HCV transmission and address the hepatitis C epidemic.

Although treatment cost appears to be the principal barrier to HCV screening, diagnosis, and treatment among prisoners and other populations, there are several other barriers that must also be considered. Like HIV, Hepatitis C has a “cascade of care” that begins with screening and proceeds through the following steps: receipt of screening test results, linkage to care, receipt of confirmatory and diagnostic test results, initiation of treatment, adherence to treatment, and attainment of SVR.⁷⁴ HCV patients may be lost to follow-up at any point in this cascade, prior to achieving SVR.⁷⁴ The AASLD and IDSA guidelines include a summary of frequently cited patient-related and practitioner-related barriers to HCV treatment initiation along with strategies to address them.²⁸ Patient-related barriers include contraindications, and lack of acceptance and/or access to treatment.^{28,75} Practitioner-related barriers include the following: perception of real or presumed patient-related barriers; lack of expertise in caring for HCV-infected patients; lack of available specialty referral resources; and concerns about either HCV treatment cost or treating persons with SUD, or both.²⁸

Patient-related barriers and practitioner-related barriers significantly affect all hepatitis C infected persons, but prisoners are particularly affected. Comorbid medical or psychiatric conditions and SUD, especially IDU, are prevalent among prisoners and relative treatment contraindications, presently used to contain costs by restricting access to treatment.^{19,28,32,33,50} Counseling, education, and referral to applicable services are among recommended strategies to address this barrier, but changes to policy and practice are currently even more important, such

as relaxation of Medicaid restrictions and treatment prioritization recommendations.^{28,32,33,50} The AASLD and IDSA emphasizes “recent and active IDU should not be seen as an absolute contraindication to HCV therapy.” Since treating HCV-infected PWID may reduce HCV incidence and prevalence by curing those at greatest risk for transmission, which is essential to control the HCV epidemic, this high-risk population should receive HCV treatment in combination with other multidisciplinary interventions and services to reduce reinfection risk and manage social and psychiatric comorbidities.^{28,44} With corrections systems at the intersection of the triad of epidemics, the prison system may be the ideal setting to offer integrated, multidisciplinary services and treatment for both HCV and SUD, to target all three epidemics. The Criminal Justice Kentucky Treatment Outcome Study’s (CJKTOS) examination of KDOC substance abuse treatment program (SAP) participants’ 12-month post-release data revealed the following positive outcomes: decreased substance use and recidivism; program satisfaction; increased recovery supports and employment; improved family relationships, mental and emotional wellbeing, and self-esteem; and reduced cost to the community.⁴¹ Incorporating HCV screening and treatment into KDOC SAPs may be an important place to start expansion of these services in Kentucky prisons, to incentivize treatment of SUD, to treat HCV-infected PWID prior to release, and to address the triad of epidemics through an integrated program that could also evaluate HCV treatment to cure as a primary prevention strategy, while seeking funding sources to further expand hepatitis C best practices to the broader HCV-infected prison population in Kentucky.

The asymptomatic nature of hepatitis C, competing priorities, and treatment factors (adverse effects, duration, efficacy) may all contribute to patients’ failure to accept HCV treatment, which can be addressed through counseling and education, case management and

patient navigation services, and co-localization and integration of multi-disciplinary services, a strategy that has been effective in correctional settings.^{28,74} Treatment factors can be overcome through education, monitoring, directly observed therapy (DOT) modeled in tuberculosis treatment programs, and by using better treatment regimens such as DAAs versus older medications.²⁸

Various factors may limit access to treatment, including high cost, insurance status, geographic distance to resources, and lack of health care practitioners skilled in managing HCV.²⁸ Insurance coverage expansion and pharmaceutical company programs that assist with medication costs are additional options for addressing financial barriers.²⁸ Several previously mentioned strategies can also help overcome access barriers, including co-localization of services and collaborative, integrated patient care models, along with resourceful use of information technology such as helpful electronic health record features (e.g. performance measures, clinical decision support tools).²⁸

A strategy of particular interest to Kentucky that could help address barriers in both the general population and correctional populations is Project ECHO (Extension for Community Healthcare Outcomes), a collaborative telemedicine model that increases HCV practitioner capacity, through videoconferencing and case-based education in which HCV specialists teach rural healthcare providers how to manage HCV.^{28,75} Project ECHO's origins in New Mexico led to positive outcomes in care for prisoners and other underserved populations.⁷⁵ Furthermore, UK Hepatologist Dr. Jens Rosenau has completed Project ECHO training and is interested in starting the program in Kentucky.⁷⁶ Therefore, Project ECHO is an important, effective intervention to consider using in Kentucky correctional settings and rural Appalachia, in response to the triad of epidemics.

Last, state government officials in the Commonwealth of Kentucky may want to consider creating a task force, comprised of subject matter experts, to look at this triad of epidemics collectively for strategic planning and development of collaborative and integrative solutions to address these epidemics both separately and cohesively. The incarceration, SUD, and hepatitis C epidemics are so intricately intertwined that multidisciplinary interventions targeting the roots of all three simultaneously may be a vital part of their multi-faceted solutions.

CONCLUSION

The following excerpt from the American College of Correctional Physicians (ACCP)⁷⁷

Hepatitis C position statement provides compelling insight into the current dilemma:

If correctional facilities are enlisted to help eradicate hepatitis C within the population, we must be allocated adequate resources to implement the goal in a medically responsible way, including funding for disease surveillance, screening, medically appropriate evaluation and complete disease treatment. The benefit of any broad public health campaign is often realized by society years after individual patients are treated. We are part of the solution to this epidemic but we recognize that we cannot treat in isolation and we cannot shoulder the cost of fighting hepatitis C alone.

The triad of incarceration, opioid overdose deaths secondary to SUDs, and hepatitis C epidemics in the U.S. and the Commonwealth of Kentucky is a rapidly evolving public health threat demanding solutions. Strategies to address the hepatitis C epidemic must resourcefully consider how screening and treating HCV infected prisoners could prevent further exponential spread of these silent killers throughout the broader community in Kentucky and the U.S.

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APPENDIX

Federal Bureau of Prisons
Clinical Guidance

Evaluation and Management of Chronic HCV Infection
May 2017

PRIORITY LEVEL 1 – HIGH PRIORITY FOR TREATMENT *

- **ADVANCED HEPATIC FIBROSIS**
 - ▶ APRI ≥ 2.0 , *OR*
 - ▶ Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, *OR*
 - ▶ Known or suspected cirrhosis
- **LIVER TRANSPLANT RECIPIENTS**
- **HEPATOCELLULAR CARCINOMA (HCC)**
- **COMORBID MEDICAL CONDITIONS ASSOCIATED WITH HCV, INCLUDING:**
 - ▶ Cryoglobulinemia with renal disease or vasculitis
 - ▶ Certain types of lymphomas or hematologic malignancies
 - ▶ Porphyria cutanea tarda
- **IMMUNOSUPPRESSANT MEDICATION FOR A COMORBID MEDICAL CONDITION**
 - ▶ Some immunosuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid medical condition, but are not recommended for use when infection is present. Although data are insufficient and current guidelines are inconsistent regarding treatment of HCV infection in this setting, such cases will be considered for prioritized treatment of HCV on an individual basis.
- **CONTINUITY OF CARE FOR THOSE ALREADY STARTED ON TREATMENT**, including inmates who are newly incarcerated in the BOP.

PRIORITY LEVEL 2 – INTERMEDIATE PRIORITY FOR TREATMENT *

- **EVIDENCE FOR PROGRESSIVE FIBROSIS**
 - ▶ APRI score ≥ 1.0
 - ▶ Stage 2 fibrosis on liver biopsy
- **COMORBID MEDICAL CONDITIONS associated with more rapid progression of fibrosis**
 - ▶ Coinfection with HBV or HIV
 - ▶ Comorbid liver diseases (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis)
 - ▶ Diabetes mellitus
- **CHRONIC KIDNEY DISEASE (CKD) with GFR ≤ 59 mL/min per 1.73 m²**

PRIORITY LEVEL 3 – LOW PRIORITY FOR TREATMENT *

- Stage 0 to stage 1 fibrosis on liver biopsy
- APRI < 1
- All other cases of HCV infection meeting the eligibility criteria for treatment, as noted below under [Other Criteria for Treatment](#).

* EXCEPTIONS to the above criteria for PRIORITY LEVELS 1–3 will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities.

OTHER CRITERIA FOR TREATMENT

In addition to meeting the above criteria for Priority Levels 1–3, inmates being considered for treatment of HCV infection should:

- Have no contraindications to, or significant drug interactions with, any component of the treatment regimen.
- Not be pregnant, especially for any regimen that would require ribavirin or interferon.
- Have sufficient time remaining on their sentence in the BOP to complete a course of treatment.
 - ➔ *Inmates with high priority criteria (PRIORITY LEVEL 1), but insufficient time remaining in BOP custody, may be considered for treatment if they will have access to medications and health care providers for continuity of care at the time of release.*
- Have a life expectancy > 18 months.
- Demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated.
 - ➔ *Inmates with evidence for ongoing high-risk behaviors, e.g., injection drug use, are considered for HCV treatment on an individual basis. Referral for evaluation and treatment of substance abuse is recommended.*

CPP 13.2
Rev. 10/05

Attachment I

DEPARTMENT OF CORRECTIONS

Receiving Screening Form

INMATE
NAME _____ DATE _____ TIME _____

INMATE NUMBER _____

VISUAL OPINION

- | | | | |
|----|---|-----|----|
| 1. | Is the inmate conscious? | Yes | No |
| 2. | Does the new inmate have obvious pain or bleeding or other symptoms suggesting need for emergency service? | Yes | No |
| 3. | Are there visible signs of trauma or illness requiring immediate emergency or doctor's care? | Yes | No |
| 4. | Is there obvious fever, swollen lymph nodes, jaundice, or other evidence of infection that might spread throughout the institution? | Yes | No |
| 5. | Is the skin in poor condition or show signs of vermin, rashes? | Yes | No |
| 6. | Does the inmate appear to be under the influence of alcohol? | Yes | No |
| 7. | Does the inmate appear to be under the influence of any drug? | Yes | No |
| 8. | Are there any visible signs of alcohol or drug withdrawal symptoms? (Extreme perspiration, shakes, nausea, pinpoint pupils, cramping, vomiting) | Yes | No |
| 9. | Does the inmate's behavior suggest the risk of suicide? | Yes | No |

- | | | | |
|-----|---|-----|----|
| 10. | Does the inmate's behavior suggest the risk of assault to staff or other inmates? | Yes | No |
| 11. | Is the inmate carrying or claims to carry medication that requires constant availability? | Yes | No |
| 12. | Are there any obvious physical handicaps? | Yes | No |

IF ANSWERED YES TO ANY QUESTIONS FROM 2-12, PLEASE SPECIFY WHY IN COMMENT SECTION BELOW.

STAFF INMATE QUESTIONNAIRE

- | | | | | |
|-----|---|-----|----|-------------|
| 13. | Are you presently taking medication for diabetes, heart disease, seizures, arthritis, asthma, ulcers, high blood pressure, or psychiatric disorder? Circle condition. | Yes | No | No Response |
| 14. | Do you have a special diet prescribed by a physician? Type _____ | Yes | No | No Response |
| 15. | Do you have history of venereal disease or abnormal discharge? | Yes | No | No Response |
| 16. | Have you recently been hospitalized or recently seen a medical or psychiatric doctor for any illness? | Yes | No | No Response |
| 17. | Are you allergic to any medication? | Yes | No | No Response |
| 18. | Have you fainted recently or had a recent head injury? | Yes | No | No Response |
| 19. | Do you have epilepsy? | Yes | No | No Response |
| 20. | Do you have a history of tuberculosis? | Yes | No | No Response |
| 21. | Do you have diabetes? | Yes | No | No Response |
| 22. | Do you have hepatitis? | Yes | No | No Response |
| 23. | Do you have a painful dental condition? | Yes | No | No Response |

24. Do you have any other medical problem we need know about? Yes No No Response

25. Do you have an alcohol or drug use history? Yes No No Response

If so, what type _____ How much _____
 For how long _____ Last Used _____
 How often _____

Any additional comments (i.e., unusual behavior):

For Staff Member to Complete: This inmate has been informed how to access health services and the grievance system upon his admission. YES NO

 Staff Signature